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Dräger medical

A Dräger and Siemens Company

Setup and Installation Manual

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Narkomed Mobile Anesthesia System

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Introduction

This manual provides the basic information needed to set up and install a Narkomed Mobile anesthesia machine. The setup and installation shall be followed by the performance of the PMC Procedure as specified in Section 6. The setup, testing and PMC must be performed by or under the direct supervision of an authorized Draeger Medical, Inc. representative. The instructions are divided into the following sections:

Section 2 gives information relating to the movement of the Narkomed Mobile Unit..

Section 3 outlines installation of breathing circuit components, sensors, and optional equipment such as vaporizers, scavenger systems, and cable arm.

Section 4 provides instructions for connecting the gas supplies to the anesthesia machine, along with the precautions to be observed when installing the cylinders and connecting the pipeline supplies.

Section 5 provides instructions for connecting the anesthesia machine to electrical power and verifying correct power-up indication on the machine.

Section 6 provides instructions for testing and performing Periodic Manufacturer's Certification(PMC) to ensure that the machine is ready for service.

WARNINGS Warning statements are used in this manual with procedures which if not performed correctly could result in personal injury.

CAUTIONS Caution statements are used in this manual to alert service personnel to the possibility of damage to the equipment if a procedure is not performed correctly.

NOTES Note statements are used in this manual to clarify information that may not be readily obvious, such as a secondary cause and effect.

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Getting the Machine Ready to Move

Please refer to the Operator's Manual, Chapter 1, page 4, for instructions on the necessary precautions and proper movement of the Narkomed Mobile Unit

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Setup and Installation

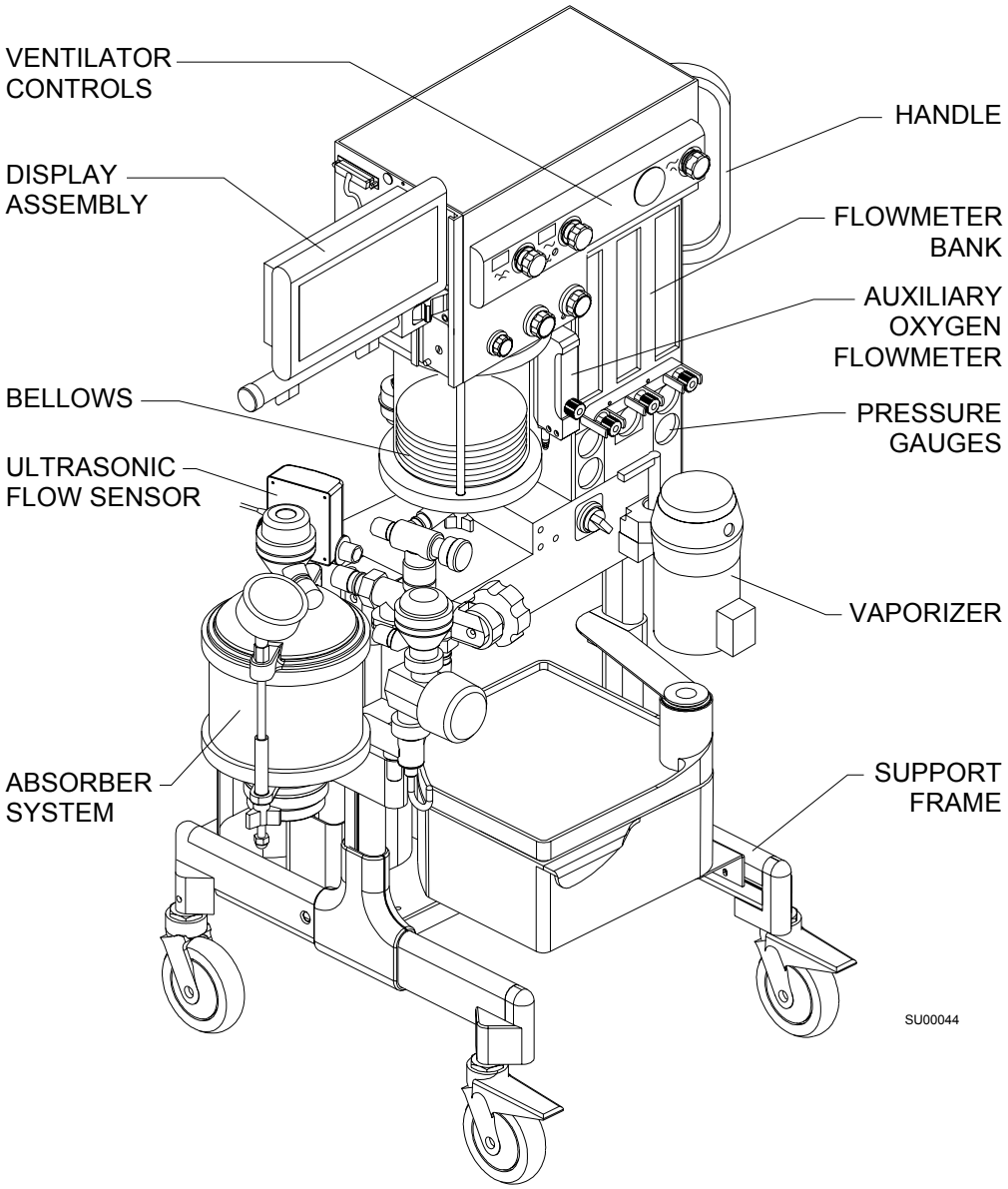
Setup Checklist

The following is a checklist for the initial setup of a Narkomed Mobile Anesthesia Machine. This setup must be performed by or under the direct supervision of an authorized Draeger Medical, Inc. Service Representative.

1. Install the vaporizer.
2. Install the absorber system.
3. Install ultrasonic flow sensor.
4. Install the breathing pressure sensor adapter.
5. Install the oxygen sensor.
6. Connect the breathing circuit and breathing bag.
7. Install the scavenger.
8. Connect the scavenger.
9. Install the display assembly.
10. Connect the gas supplies.
11. Connect the power cord.
12. Perform a Periodic Manufacturer's Certification (PMC) procedure. This procedure must be performed by an authorized Draeger Medical, Inc. Service Representative as part of the initial setup.

The Testing and Periodic Manufacturer's Service Procedures provided in Section 6 of the Service Manual *must be performed at initial installation, and prior to use following any extended storage period*. This procedure ensures that the anesthesia machine is working properly, which is critical to the health and safety of the patient and the operator.

Figure 3-1. Narkomed Mobile (assembled)



Installing the Vaporizer

If a vaporizer is dropped during handling, or if its handwheel exhibits a lack of resistance (spins freely), or if a gas analyzer maintains a zero reading after the handwheel has been turned to a labeled concentration, do not use the vaporizer. Return the vaporizer to the Draeger Medical, Inc. Technical Service Department.

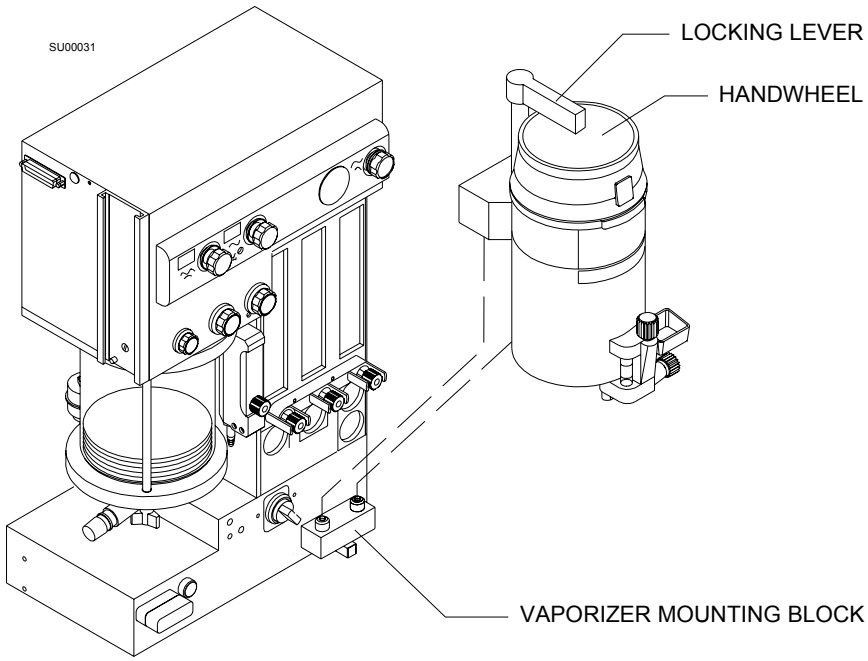
Caution: Handle the vaporizer with care. Do not drop, carry by the handwheel, sealing plug, or locking lever. Damage to the vaporizer will result.

To install the vaporizer:

Verify that the vaporizer handwheel is locked in zero position.

Place the vaporizer on the ports in the vaporizer mounting block and turn the locking lever clockwise 90° until the vaporizer is locked securely on the mounting block on the front of the machine.Ensure the presence and integrity of the o-rings.

Figure 3-2. Installing the Vaporizer



Filling the Vaporizer

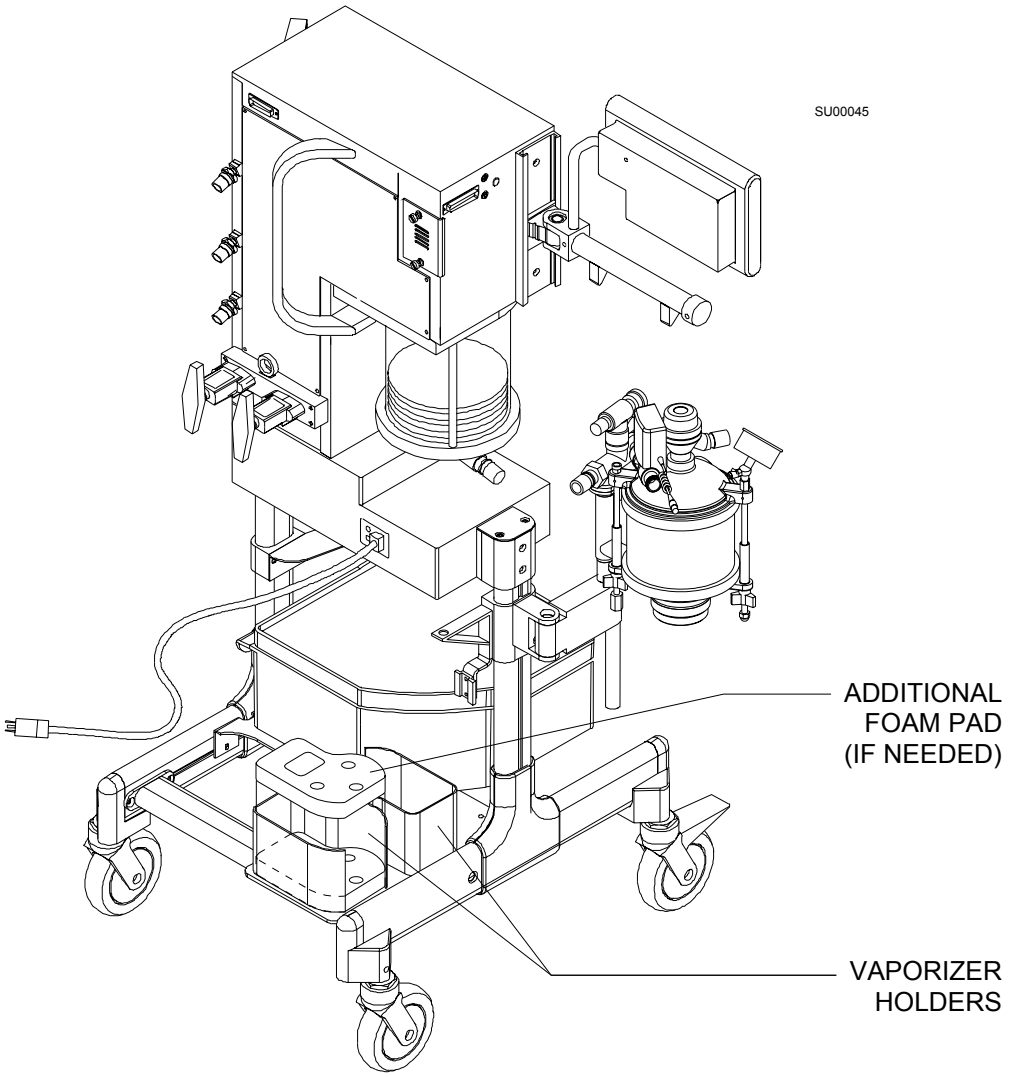
See the appropriate separate manual, supplied with vaporizers available for use with the Narkomed 6000.

Vaporizer Storage

Two vaporizer holders are located on the lower rear frame rail as shown in the illustration.

Each holder will accommodate a single Dräger Vapor unit. For storing a Dräger Vapor unit with a flat bottom, a single foam cushion is used. For Dräger Vapor units that are not the flat bottom style (three exposed pads on the bottom of the unit) you will need to place an additional foam cushion in the holder. There are two additional foam cushions supplied with the machine and are located in the drawer.

Figure 3-3. Vaporizer Storage Locations



Installing the Absorber System

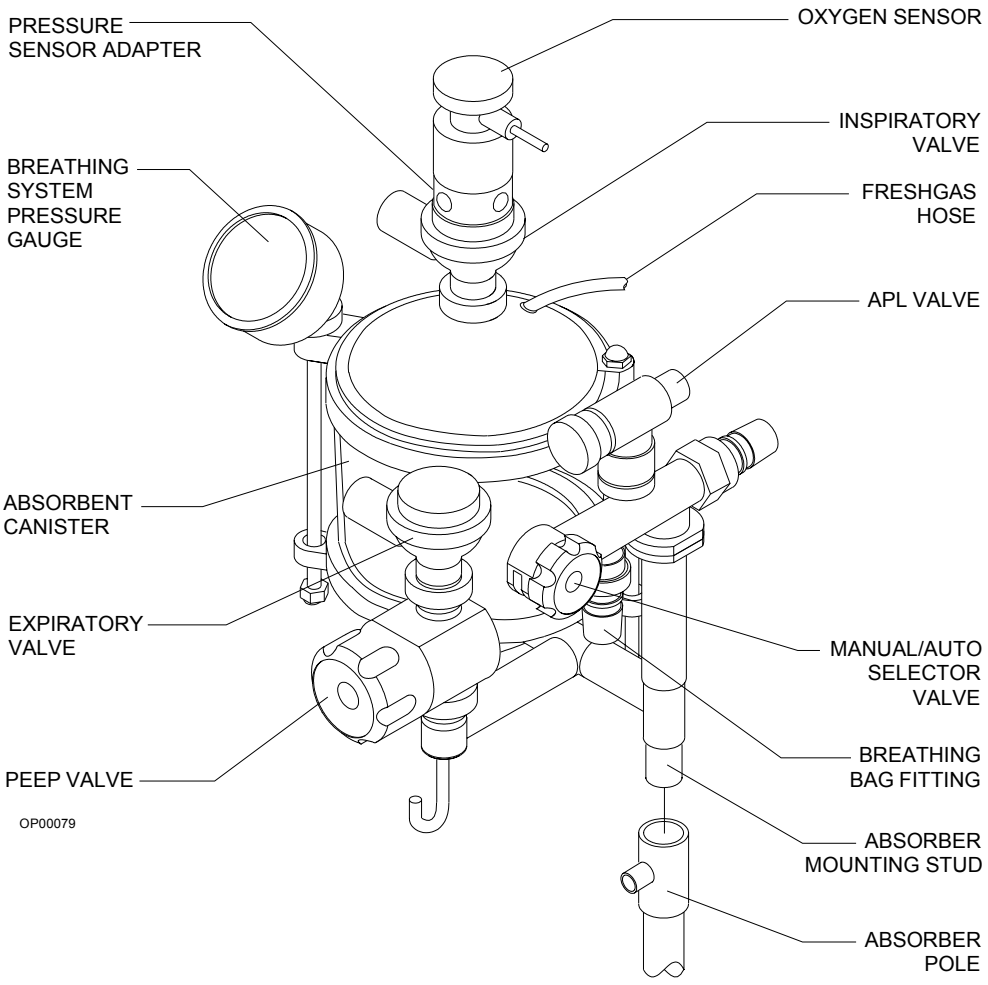
Install the absorber system as described below.

1. Place the absorber mounting stud into the absorber pole and tighten the set screw to lock the assembly to the absorber pole.
2. Loosen the absorber arm wing screw to raise the absorber system to the preferred height and position. Tighten the wing screw to hold the absorber at that height.

   Warning: Do not pinch or kink the fresh gas hose leading from the fresh gas outlet to the absorber.

3. Connect the fresh gas hose to the fresh gas outlet on the machine.

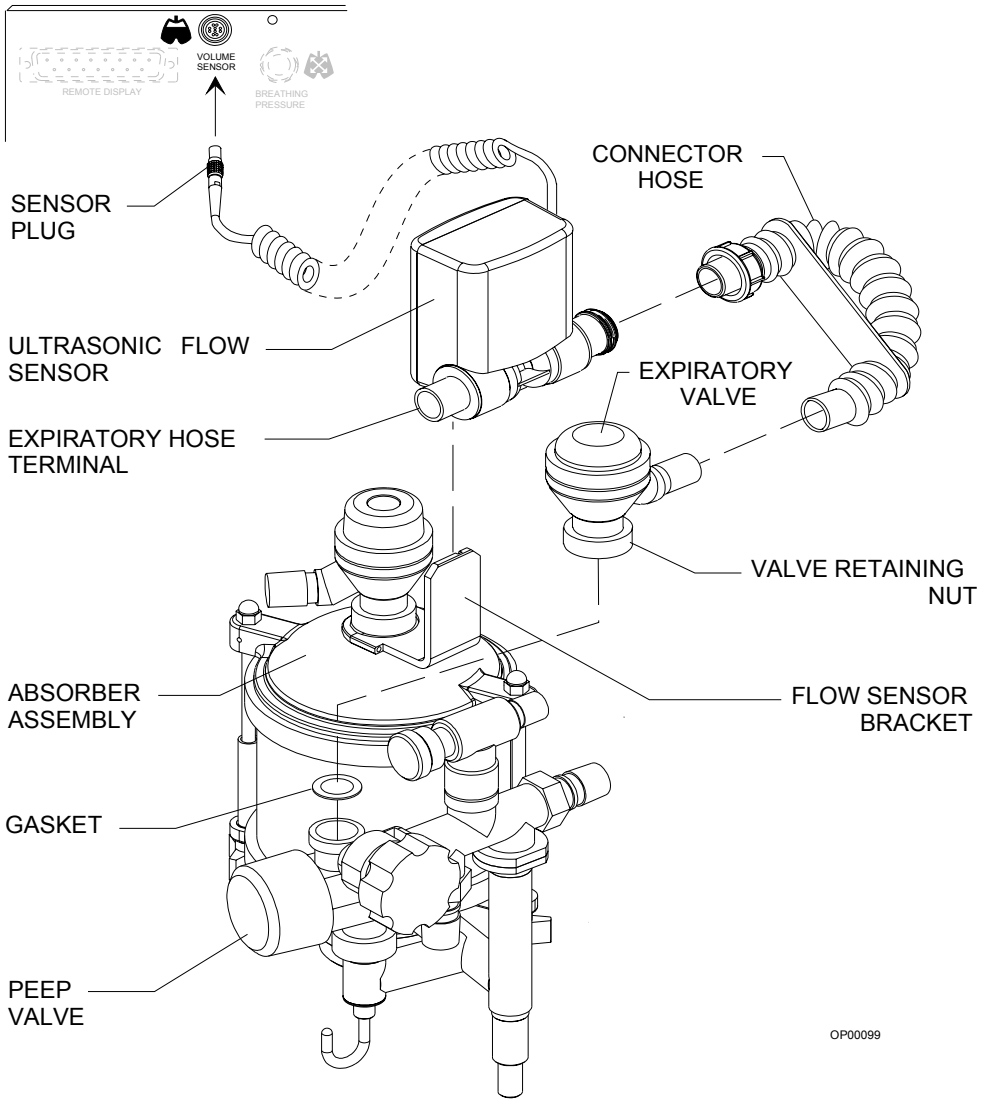
Figure 3-4. Attaching the Absorber Assembly to the Absorber Pole



Installing and Connecting the Ultrasonic Flow Sensor

Install and connect the ultrasonic flow sensor as outlined in the figure below.

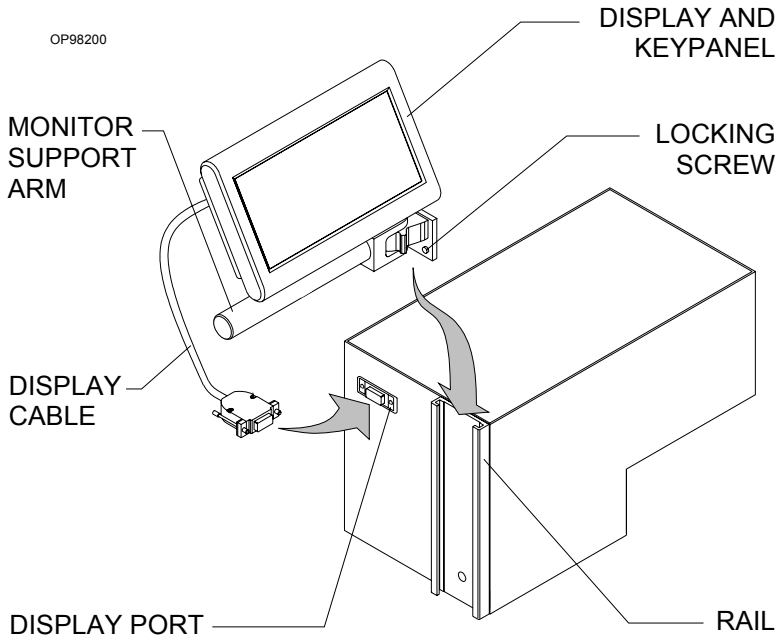
Figure 3-5. Attaching the Ultrasonic Flow Sensor



Installing and Connecting the Display and Monitor Support Arm

1. Slide the display and monitor support arm assembly into the rail on the left side of the monitor housing. Hold the assembly at the preferred height and tighten its locking screw to hold it in position.
2. Connect the cable from the display panel to the remote display port on the side of the machine. Slide the retaining clip portion of the cable plug to the left. This will lock the cable plug to the control box. To disconnect the display cable, slide the retaining clip to the right and gently remove the cable plug. Never remove or install this plug when the unit is powered up.

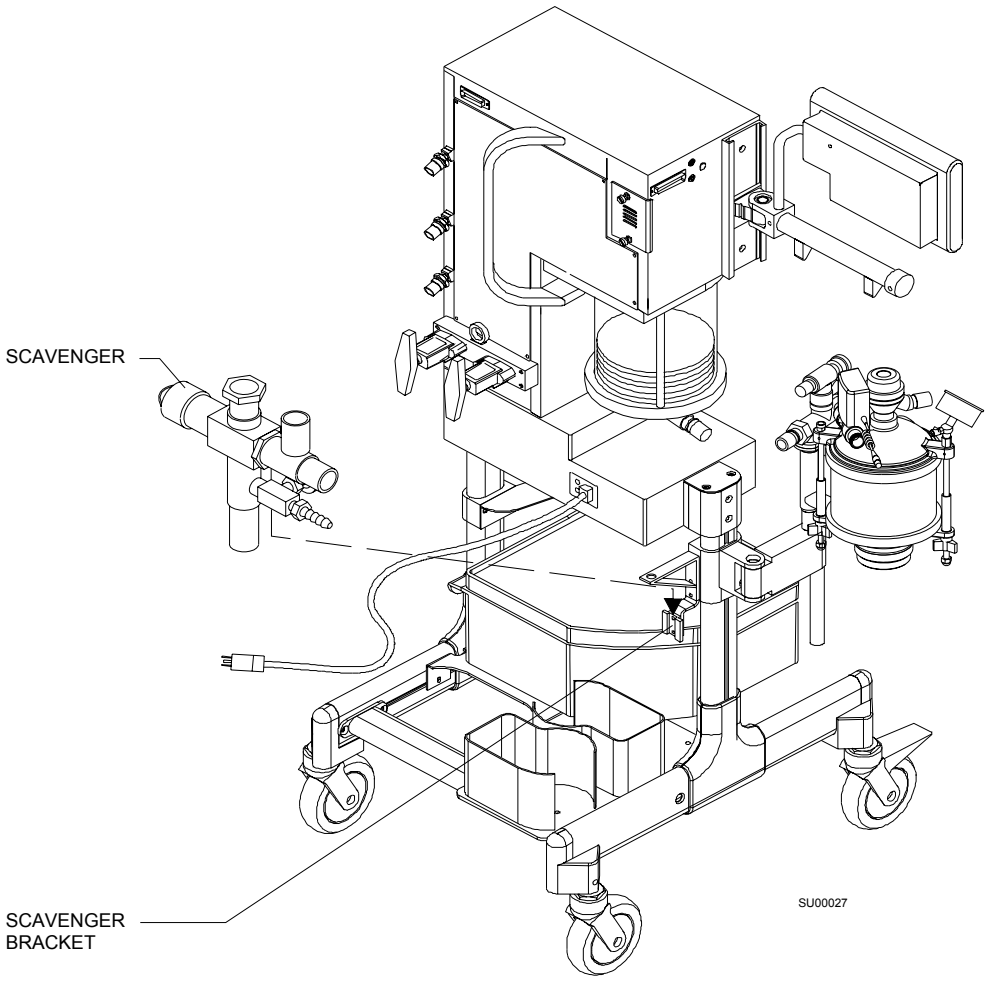
Figure 3-6. Installing the Display and Monitor Support Arm



Installing the Scavenger

1. Remove the scavenger from its box.
2. Slide the bracket on the scavenger over the slide mount located on the top back bar of the support frame.

Figure 3-7. Installing the Scavenger

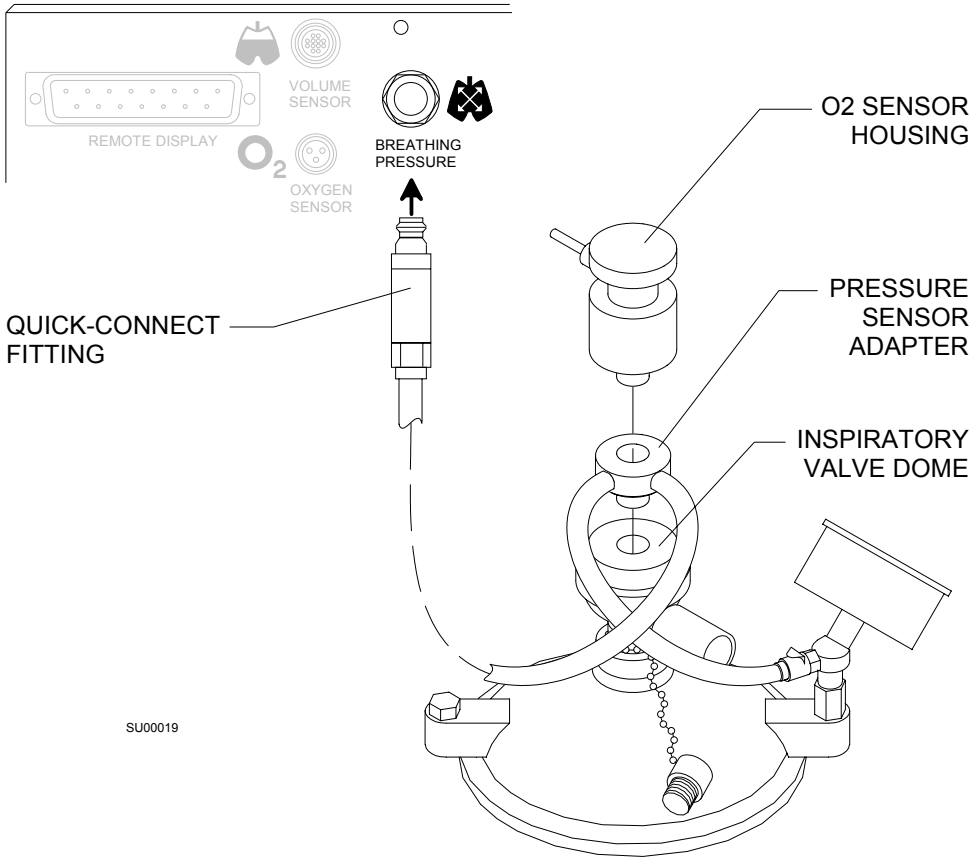


Installing and Connecting the Breathing Pressure Sensor Adapter

Install the breathing pressure sensor adapter as shown in the illustration.

1. Pull the inspiratory valve dome plug from the inspiratory valve dome.
2. Insert the pressure sensor adapter into the inspiratory valve dome by pressing it into place. Verify that there is a line connected to the hose barb on the adapter and that the line is secured with a press-on clamp.
3. Join the connector on the hose assembly to the breathing pressure monitor connector on the side of the monitor housing.

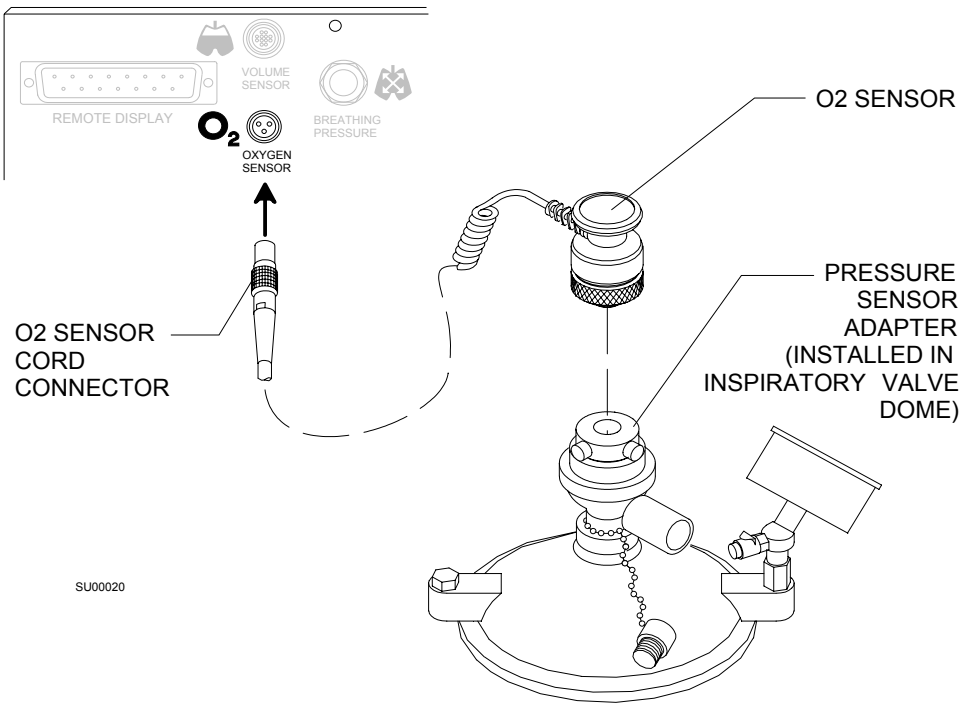
Figure 3-8. Installing the Breathing Pressure Sensor Adapter



Installing and Connecting the Oxygen Sensor

1. Connect the sensor cord to the O_2 SENSOR receptacle on the side of the monitor housing.
2. Remove the cap from the sensor housing.
3. Perform an oxygen sensor calibration as described in “Calibrating the Oxygen Sensor” in the Narkomed Mobile Operator’s Manual.
4. Press the sensor housing into the pressure sensor adapter.

Figure 3-9. Connecting the Oxygen Sensor



Connecting the Breathing Circuit and Breathing Bag

Warning: The Narkomed Mobile patient breathing system must not be used in conjunction with any additional components that establish a flow direction.

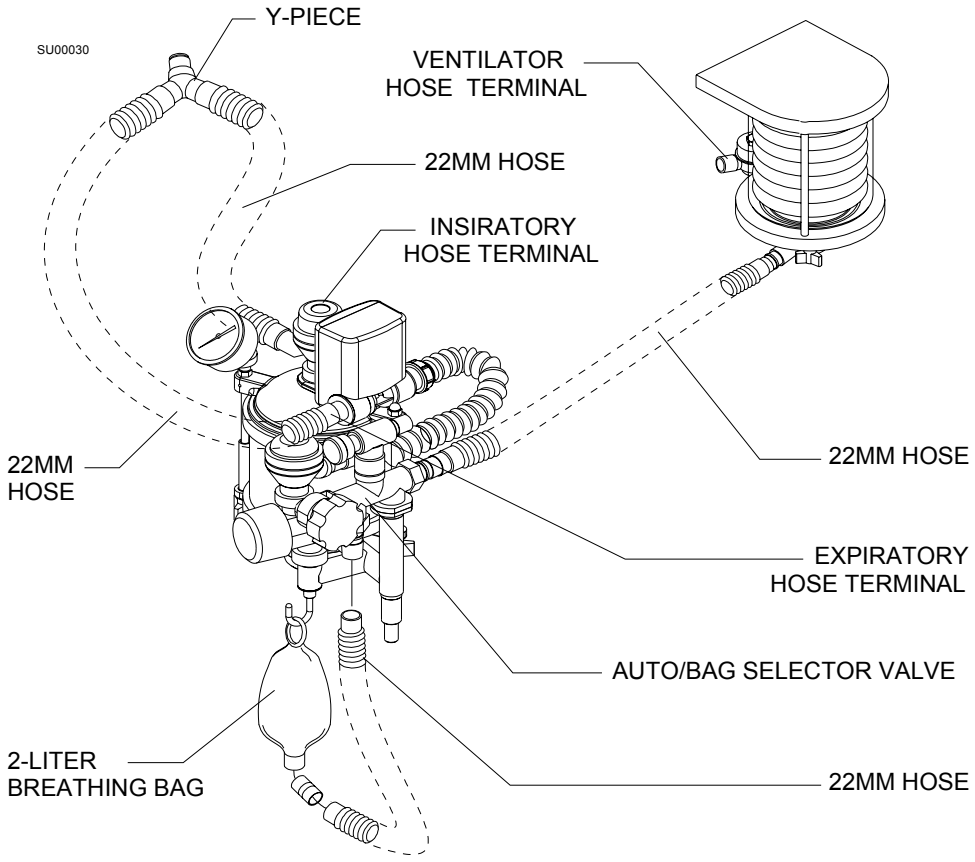
Warning: Hoses and bags attached to the 22 mm hose terminals of the inspiratory valve, expiratory valve, ventilator hose connection, and breathing bag mount must comply with current ASTM standards.

Warning: To prevent leaks and misdirection of gas pathways, all hoses should be correctly and tightly fitted, as shown in the illustrations. Take special care to make sure that all 19 mm hoses are attached to the proper 19 mm connectors. Possible machine malfunction and harm to the patient could occur if the scavenger hoses are attached to any 22 mm connection.

1. Attach a 22 mm breathing hose between the ventilator bellows 22 mm terminal marked VENTILATOR HOSE, and the 22 mm terminal on the rear of the manual/automatic selector valve marked VENTILATOR HOSE.
2. Attach a 22 mm breathing hose between the 22 mm hose terminal on the inspiratory valve marked INSPIRATION, and one side of the Y-piece.

   Warning: To ensure proper direction of gas flow during inspiratory and expiratory phases, the disks in the inspiratory and expiratory valves must move freely, without sticking.
3. Attach a 22 mm breathing hose between the other side of the Y-piece and the 22 mm hose terminal on the ultrasonic flow sensor.

Figure 3-10. Connecting the Breathing Circuit and Breathing Bag



4. Attach a breathing bag, with a 22 mm extension hose to the terminal on the bottom of the manual/automatic selector valve. Place the breathing bag hanger loop on the hook below the selector.

   Warning: The breathing bag acts as a pressure-limiting device during manually assisted and spontaneous ventilation. Breathing bags used with the absorber system must comply with the pressure/volume requirements of current ASTM standards. A breathing bag that has been previously stretched may have drastically altered compliance characteristics, and altered conductivity in the case of conductive bags.

Connecting the Scavenger System

The scavenger interface can be connected to a suction system or passive waste gas removal system. Before installing the scavenger, determine which system will be used.

1. Connect a 19 mm hose between the 19 mm terminal labeled SCAVENGER HOSE on the ventilator relief valve and the 19 mm terminal labeled SCAVENGER HOSE on the left side of the scavenger.

   Warning: The 19 mm scavenger hose leading from the ventilator relief valve must not be pinched, kinked, or blocked in any manner.

   Warning: Take special care not to accidentally force 19 mm scavenger hoses over 22 mm breathing hose terminals. Carefully follow the hose connection instructions for installing the scavenger and the absorber.

2. Connect a 19 mm hose between the 19 mm terminal labeled SCAVENGER HOSE on the back of the APL valve and the 19 mm terminal labeled SCAVENGER HOSE on the right side of the scavenger.

   Warning: The 19 mm scavenger hoses leading from the absorber system must not be pinched, kinked, or blocked in any manner.

3. If a passive system is used, connect the exhaust hose to the waste gas exhaust port at the bottom of the scavenger. Make sure the needle valve is turned off.

   If a suction system is used, connect the vacuum hose to the vacuum hose terminal on the scavenger and attach the 3-liter bag with the magenta coupling to the waste gas exhaust port at the bottom of the scavenger.

4. For suction systems perform an initial adjustment on the needle valve.

   a. Attach a breathing bag and a Y-piece to the absorber system.

   b. Attach the bag adapter and a solid black breathing bag to the Y-piece.

   c. Set the manual/automatic selector valve to BAG and set the ventilator to the preferred frequency.

Figure 3-11. Connecting the Scavenger Interface for Passive Systems

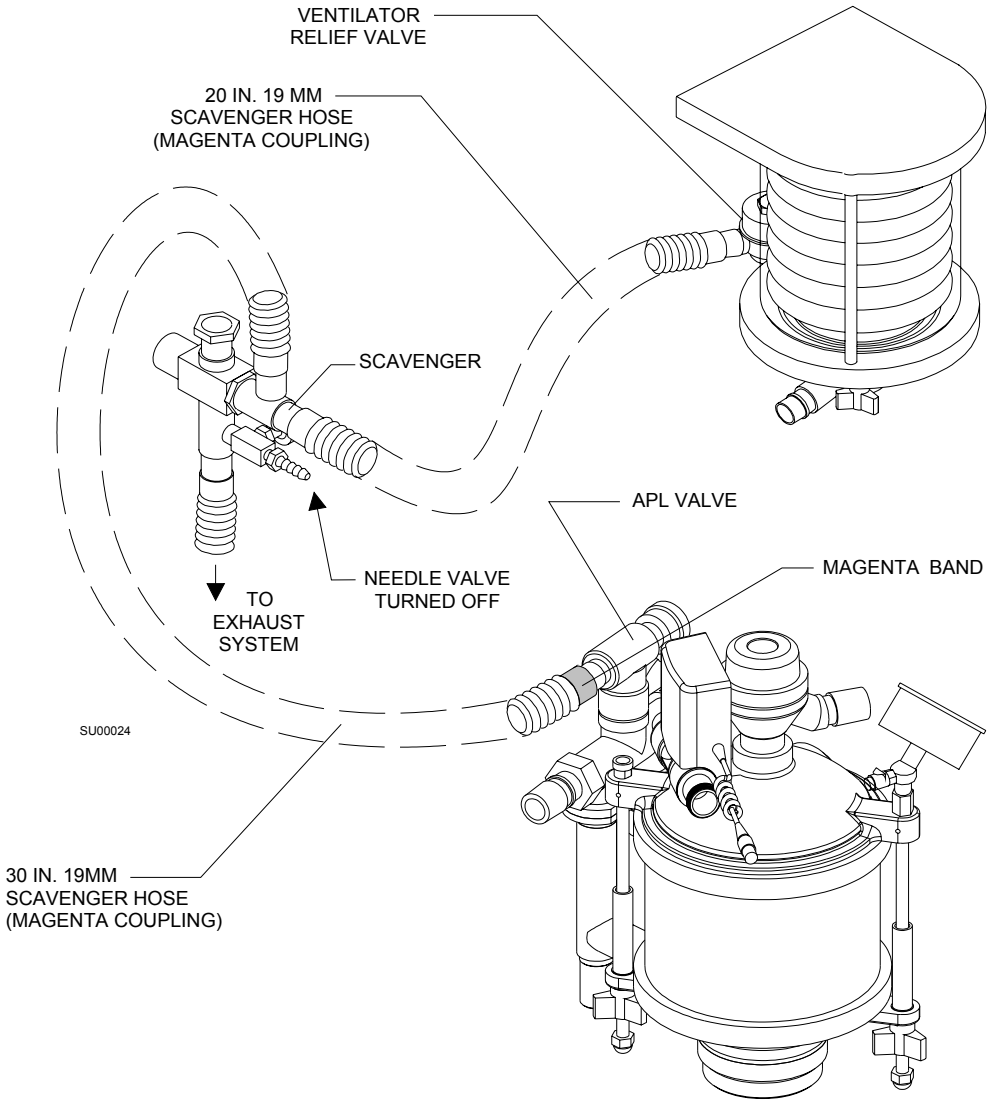
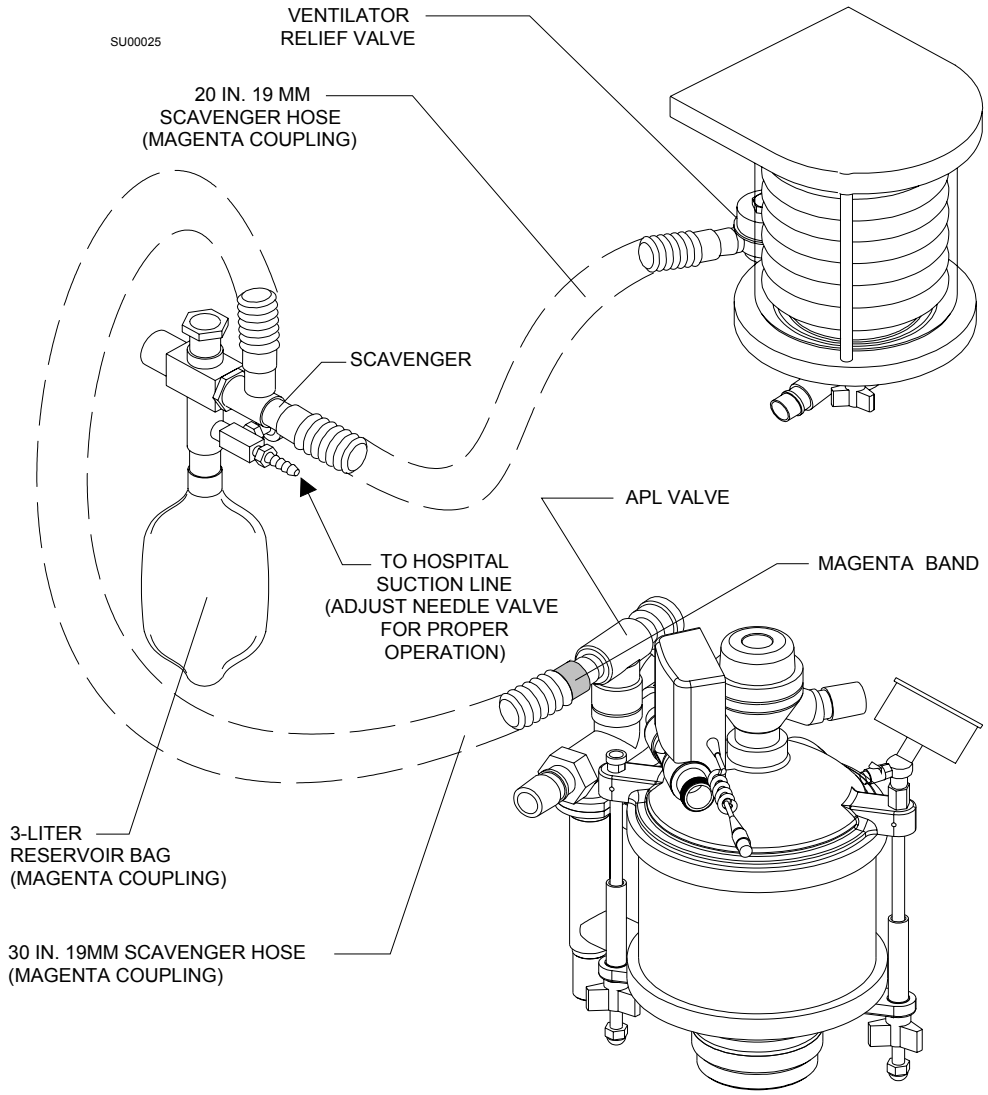


Figure 3-12. Connecting the Scavenger Interface for Suction Systems


SU00025
VENTILATOR RELIEF VALVE
20 IN. 19 MM SCAVENGER HOSE (MAGENTA COUPLING)
SCAVENGER
APL VALVE
TO HOSPITAL SUCTION LINE (ADJUST NEEDLE VALVE FOR PROPER OPERATION)
MAGENTA BAND
3-LITER RESERVOIR BAG (MAGENTA COUPLING)
30 IN. 19MM SCAVENGER HOSE (MAGENTA COUPLING)

d. Adjust the O2 flow control valve to the expected total flow of all gases.

e. Verify that the suction disposal system is active.

f. Watch the scavenger reservoir bag as the oxygen flow passes through the scavenger. The bag should not overextend or collapse.

g. Adjust the needle valve to provide either more or less suction.

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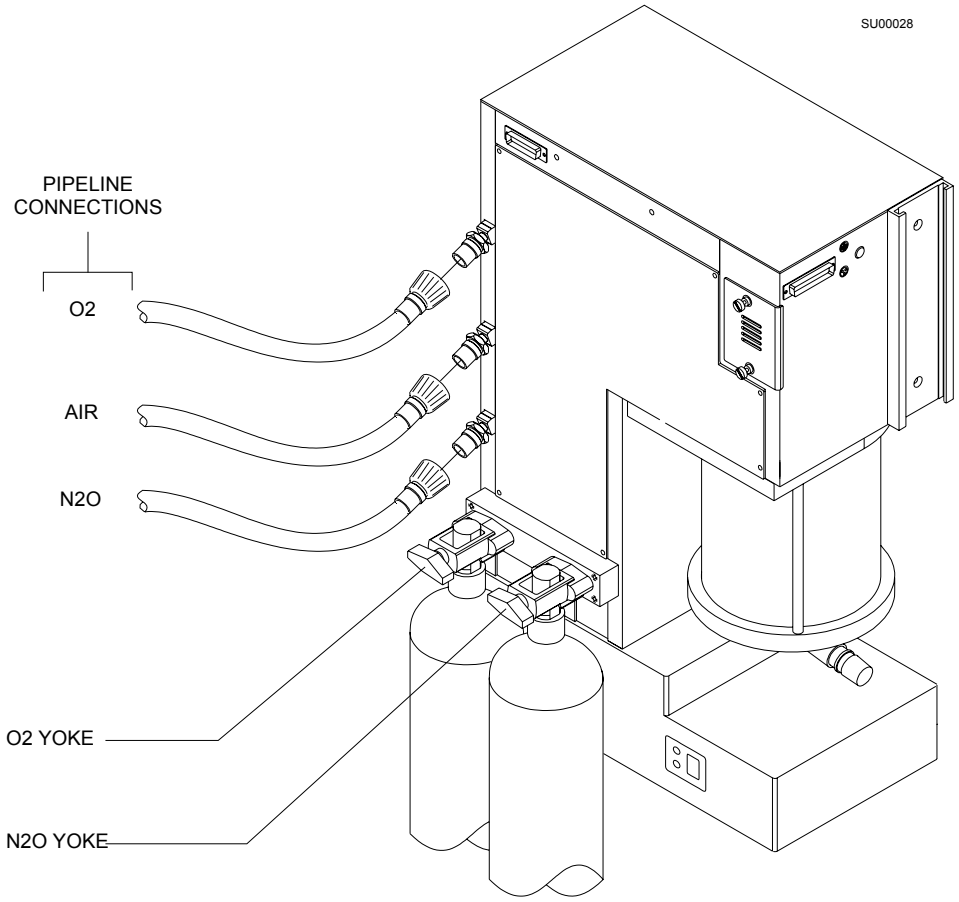
Gas Supply Connections

The location of the gas supply connections on the Narkomed Mobile anesthesia machine is shown in the illustration. Details of the cylinder yokes and the pipeline connections are given in the following paragraphs:

Figure 4-1. Gas Supply Connections



Connecting the Cylinders

The Narkomed Mobile is equipped with ANSI standard pin-indexed hanger yokes for E-size gas cylinders.

WARNING:

Oil and grease may combine explosively with oxygen or nitrous oxide. For this reason, oil and grease must never come in contact with pipelines, cylinders, cylinder valves, gauges, fittings, etc., which conduct oxygen or nitrous oxide within the machine. For further information regarding safety precautions in the use of medical gases, consult Compressed Gas Association pamphlet P-2 and appropriate sections of National Fire Protection Association Standard 99.

Attach the cylinders as follows:

1. Place a new washer on the seat of the yoke gas inlet connection.

Warning:

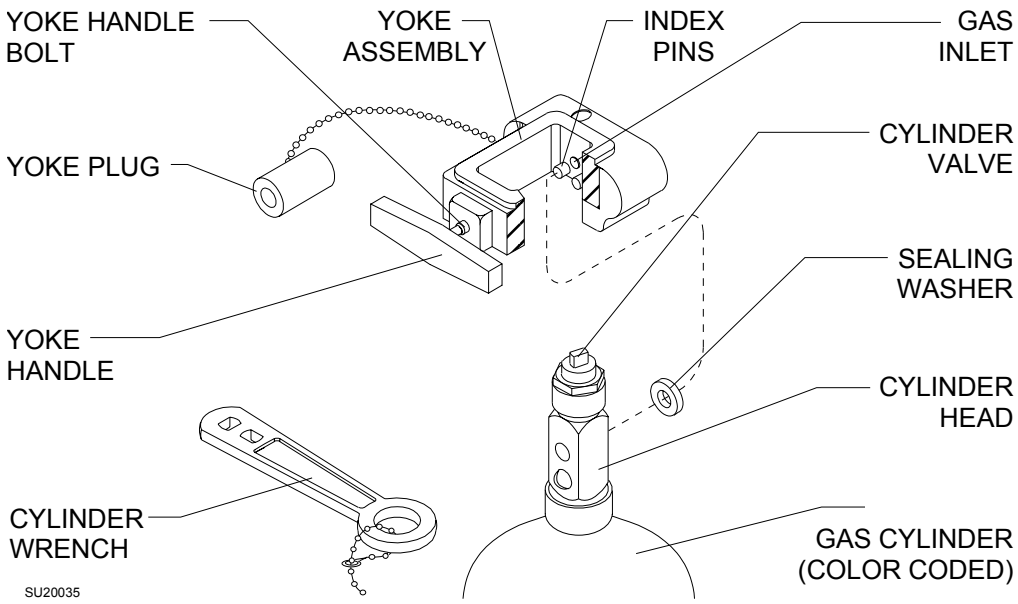
Use only one cylinder washer per yoke. Using more than one washer could cause leakage of the cylinder gas and compromise the pin indexing system.

2. Verify the presence and integrity of the two index pins below the gas inlet.

Warning:

Check cylinder yokes for the presence of two index pins each time a cylinder is attached to the machine.

Figure 4-2. Cylinder Yoke Arrangement



3. Insert the head of a gas cylinder with matching gas into the yoke from below, so that the gas outlet and indexing holes on the cylinder head are facing the gas inlet and indexing pins on the yoke assembly.

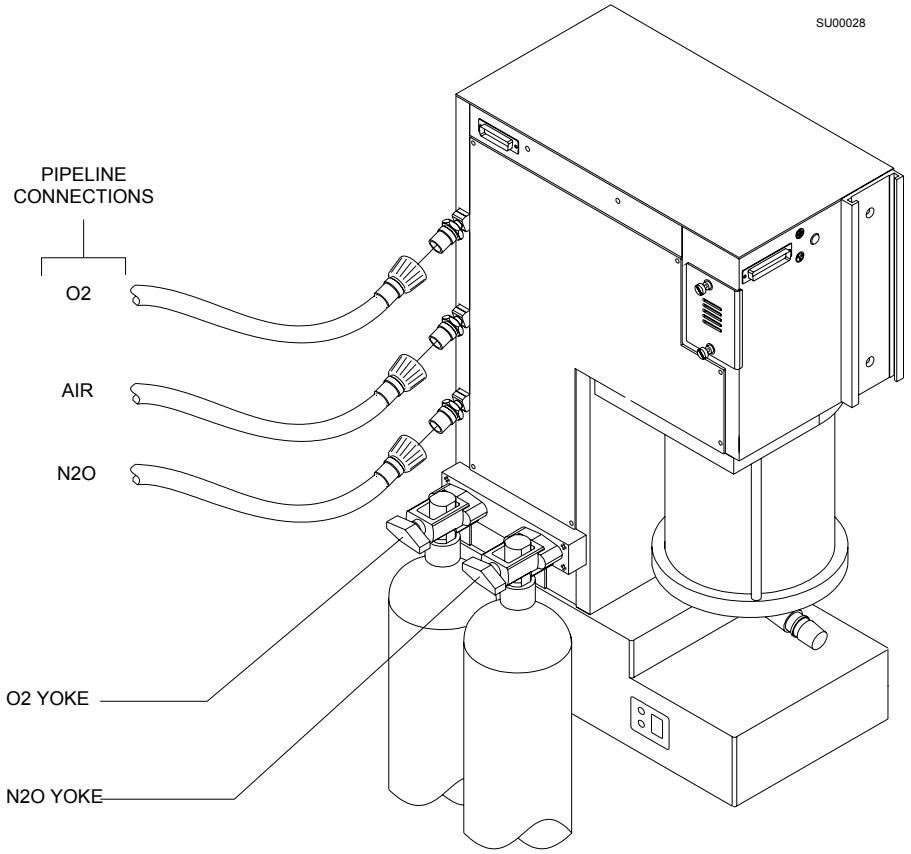
4. Engage the indexing holes with the index pins. Screw the yoke handle clockwise against the cylinder head, so that the point of the yoke handle is aligned with the countersunk recess on the back of the cylinder head.

5. Verify that the sealing washer is in place, that the index pins are engaged, and that the cylinder hangs vertically. Tighten the handle securely.

Connecting the Pipelines

Pipeline connections for oxygen, nitrous oxide and air are located on the rear of the machine. The pipeline inlets are labeled for each gas and are arranged as shown in the illustration. Gas system color coding is shown in the table below.

Figure 4-3. Pipeline Inlets and Connections



GAS SYSTEM COLOR CODING		
GAS	**MARKING**	**U.S.A.**
Air	**AIR**	Yellow
Nitrous Oxide	**N_2O**	Blue
Oxygen	**O_2**	Green

WARNING:

Oil and grease may combine explosively with oxygen or nitrous oxide. For this reason, oil and grease must never come in contact with pipelines, cylinders, cylinder valves, gauges, fittings, etc., which conduct oxygen or nitrous oxide within the machine. For further information regarding safety precautions in the use of medical gases, consult Compressed Gas Association pamphlet P-2 and appropriate sections of National Fire Protection Association Standard 99.

Connect The Pipeline Supply Hoses As Follows:

1. Verify that the hoses have the correct gas fittings. Connect the gas fitting on each supply hose to the corresponding gas fitting on the rear of the machine and tighten the hex nut.

WARNING:

Both ends of each gas supply hose must be indexed for the same gas. Pipeline delivery hoses used between wall outlets and anesthesia machines have caused accidents when, during assembly, an oxygen fitting has been placed on one end of the hose and a nitrous fitting on the other end.

2. Connect the other end of each supply hose to the appropriate functioning hospital pipeline outlet.

3. Check the pipeline pressure gauges on the front of the Narkomed Mobile for sufficient pipeline pressure (50—55 psi).

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Connecting the Narkomed Mobile to Electrical Power

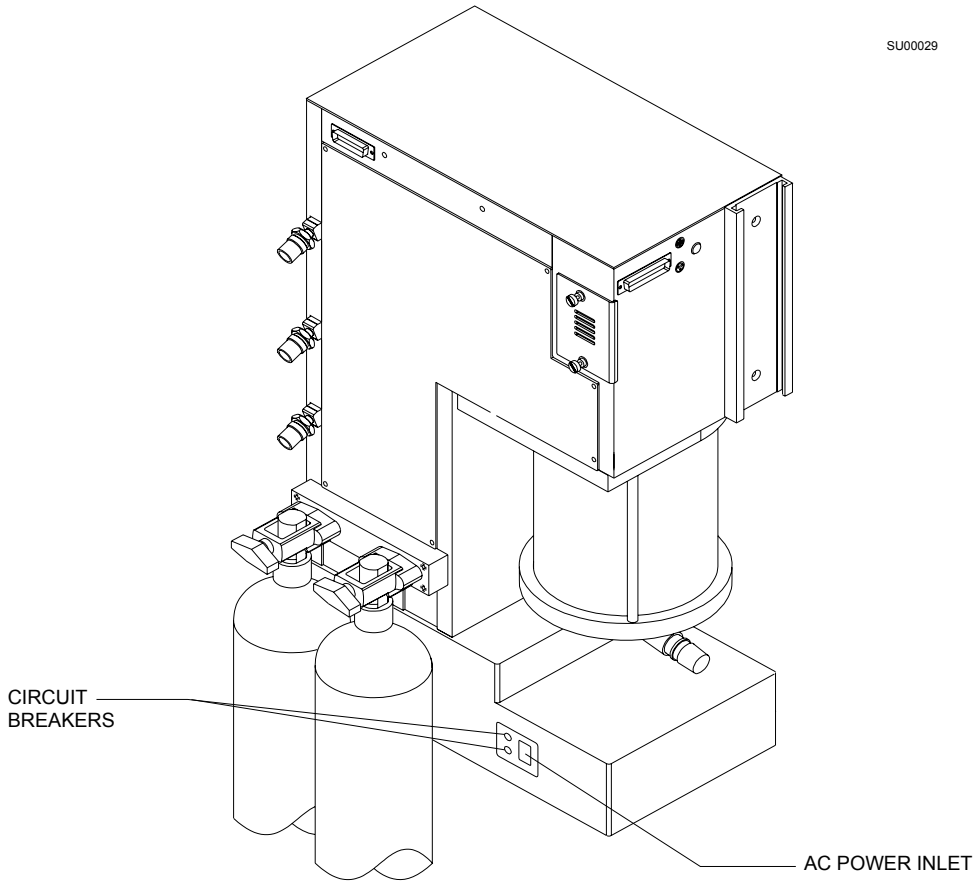
The Narkomed Mobile is equipped with a power cord and a hospital grade plug for 120 VAC primary electrical power.

Connect the Narkomed Mobile to electrical power as follows:

1. Verify that the Narkomed Mobile System Power switch is set to STANDBY.
2. Verify that all circuit breakers are in the “set” (pushed in) position.
3. Connect the female end of the power cord to the power inlet connector.
4. Plug the power cord into an active AC hospital grade outlet.

   Do not use “cheater” plugs. The term “cheater” plug implies any and all electrical plugs or other devices that can inhibit or prohibit the proper grounding of the anesthesia machine.

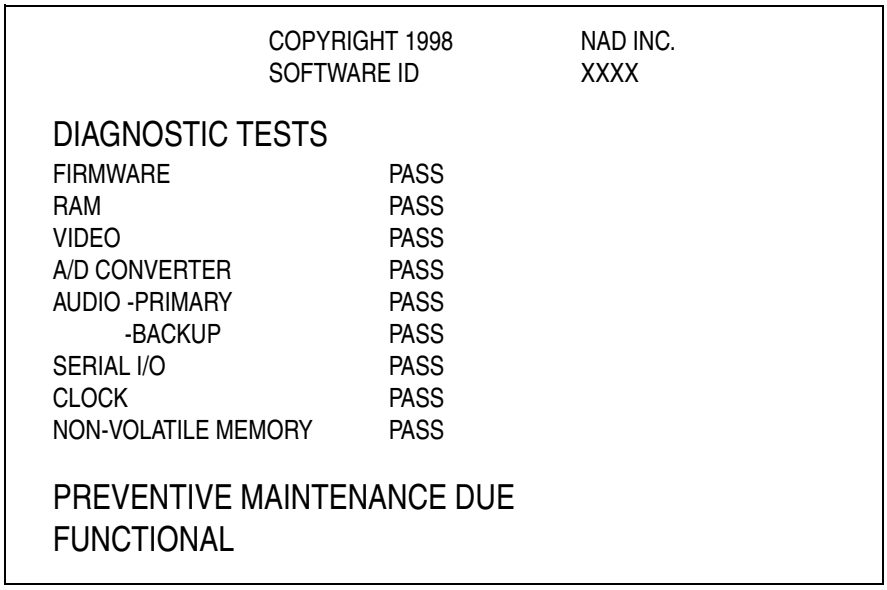
Figure 5-1. Location of Power Inlet and Circuit Breakers



Power-Up Diagnostics Test

1. Turn the Narkomed Mobile System Power switch to ON. The self-diagnostic screen is displayed. A typical power-up diagnostic screen is shown in the illustration.
2. Verify that the power on indicator light is on.
3. Verify that all circuit breakers remain in the “set” (pushed in) position.

Figure 5-2. Power-up Diagnostics Screen



6

Testing and PMS

NOTE:

The following pages in this section comprise an excerpt from the PMS section of the corresponding service manual. Therefore any revision notices on these pages will reflect the revision level at which they occurred in the *service* manual, and are not related to the revision level of this setup and installation manual.

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6.0 PMC PROCEDURE, NARKOMED MOBILE

The procedures in this section shall be performed in their entirety each time a component is removed, replaced, calibrated, adjusted and during all scheduled Periodic Manufacturer's Certification (PMC) visits. A PMC Checklist form, P/N 4115597 is available from Draeger Medical, Inc. and shall be completed by the Technical Service Representative each time a PMC is performed. Steps in the procedure marked with (✓) require a response at the corresponding line on the checklist form.

Space is also provided on the PMC checklist form to record the results of a vapor concentration test. Refer to the current Anesthesia Equipment & Monitoring System Service Information CD-ROM Service Procedures section for vapor concentration verification procedures.

NOTE: Test equipment listed below with an asterisk (*) requires calibration at a maximum interval of one year. Verify the dates on test equipment calibration labels. DO NOT USE any test equipment having an expired calibration date. Notify your supervisor immediately if any equipment is found to be out of calibration. In the space provided at the bottom of the PMC checklist form, record the Model and ID number of all calibrated test equipment used.

In the space provided at the bottom of the PMC checklist form, record the Model and ID number of all calibrated test equipment used. Also record the calibration due dates. Examples are: multimeter, digital pressure meter, Riken gas analyzer, safety analyzer, volumeter, trace gas analyzer, simulators.

Test Equipment Required:

- *Electrical Safety Analyzer (Biotek 501 Pro or equivalent)
- *Pressure Gauge with DISS Adapters (P/N 4114807 or equivalent)
- *Flowmeter 0-250 ml min. (P/N S000081 or equivalent)
- *Volume Meter (P/N 2212300 or equivalent)
- *Digital Pressure Manometer (SenSym PDM 200CD or Equivalent)
- *Riken Gas Indicator (Model 18H, or 1802D or equivalent)
- Stop Watch
- Test Lung (P/N 8401892)

Materials Required:

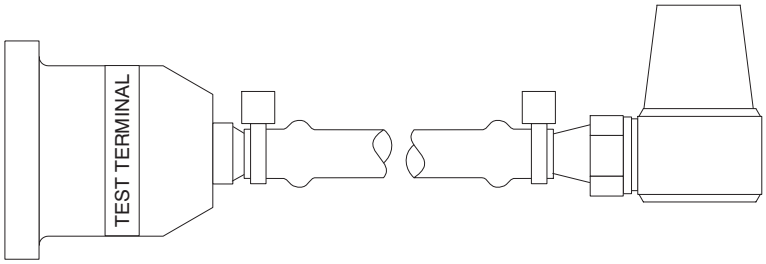
- Breathing Bag 3 liter (P/N 9995330 or equivalent)
- Patient Circuit: Y-piece, elbow, 2x 32” x 22mm hoses
- Hose 22 mm x 32” (P/N 9995132)
- Fresh Gas Outlet Volume Test Device (P/N S010158 or equivalent)
- Fresh Gas Leak Test Adapter (P/N 4115041 or equivalent)
- Volumeter/Fresh Gas Adapter (P/N 4115042)

Materials Required (continued):

- Test Terminal 2x (P/N 4104389 or equivalent)
- Breathing System Leak Test Device (P/N S010159 or equivalent)
- PDM/Suction Adapter (P/N 4115038)
- Scavenger Adapter (P/N 4108114)
- Pressure Monitor Test Adapter (P/N 4115043 or equivalent)

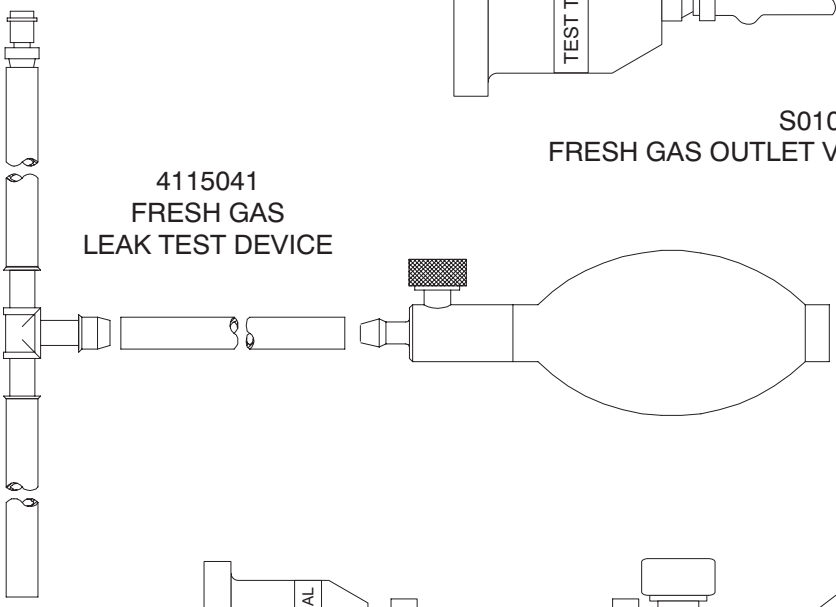
Key test equipment and materials illustrations are shown on following pages.

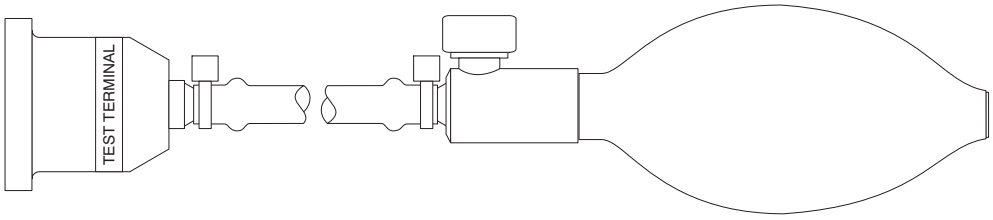
TEST EQUIPMENT AND FIXTURE ILLUSTRATIONS



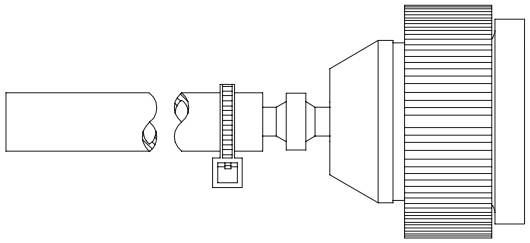
S010158
FRESH GAS OUTLET VOLUME TEST DEVICE

4115041
FRESH GAS
LEAK TEST DEVICE





S010159
BREATHING SYSTEM LEAK TEST DEVICE

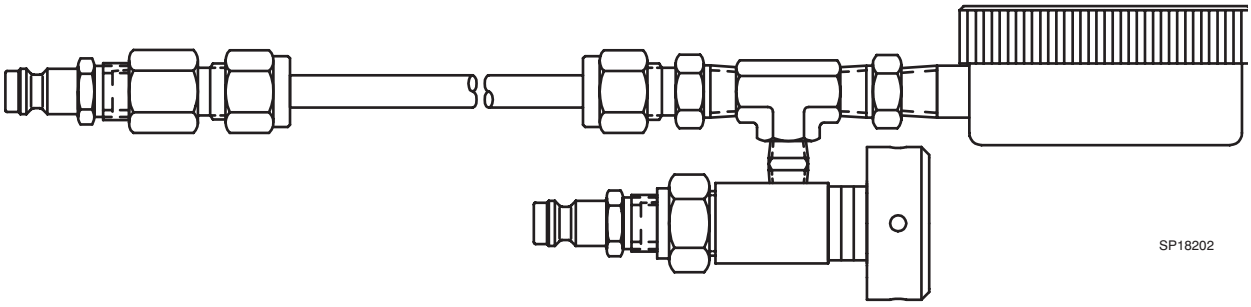


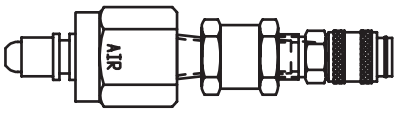
4115042
VOLUMETER/
FRESH GAS HOSE
ADAPTER

SP18201

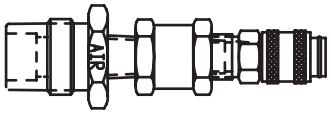
TEST EQUIPMENT AND FIXTURE ILLUSTRATIONS - Continued

4114807 PRESSURE TEST ASSEMBLY , WITH ADAPTERS

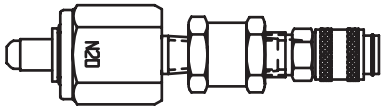




4114830-002



4114830-001



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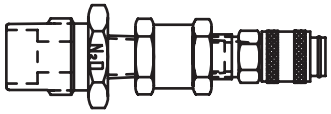

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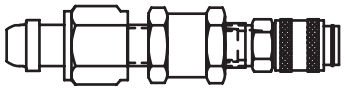

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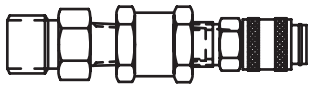
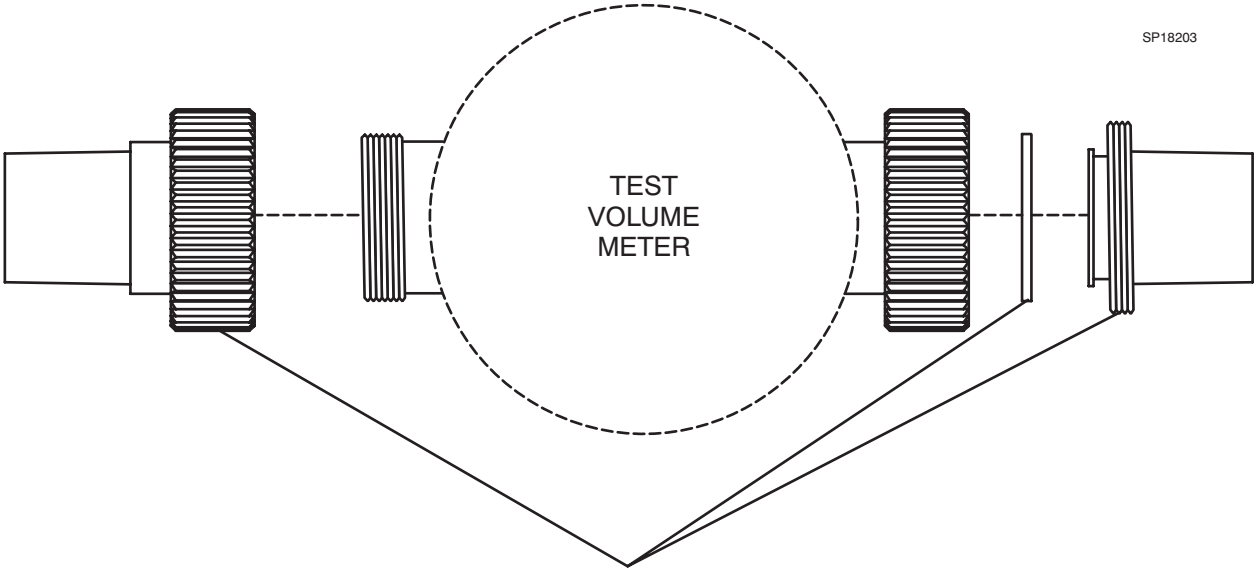


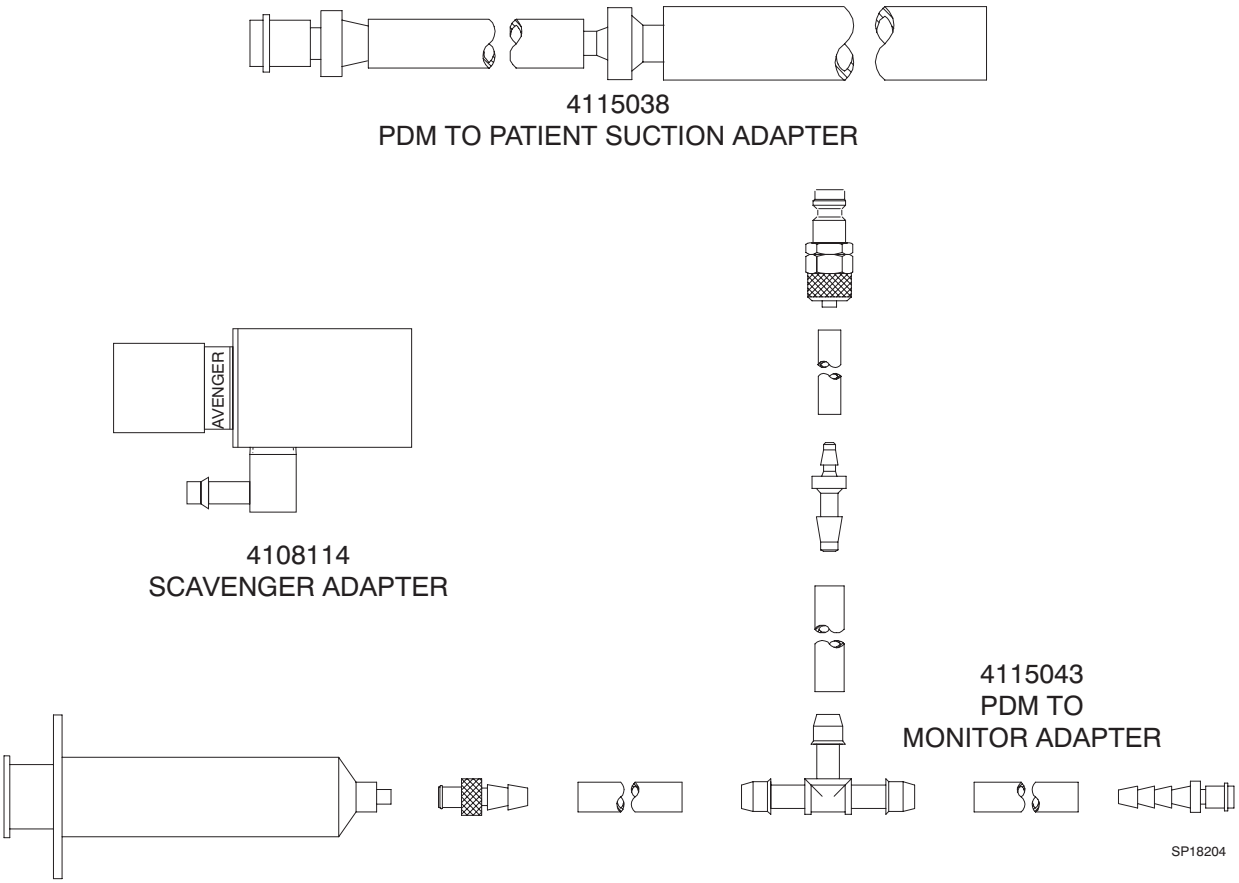
4114830-005

TEST EQUIPMENT AND FIXTURE ILLUSTRATIONS - Continued



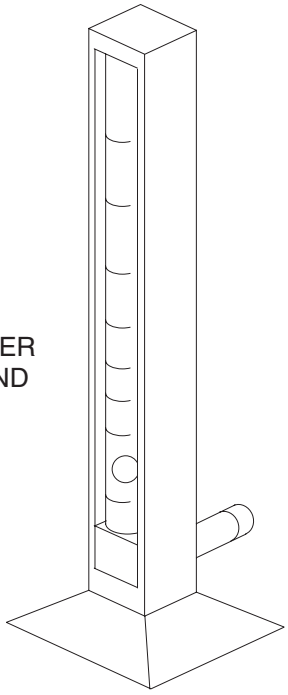
4115087 33mm x 22mm ADAPTER

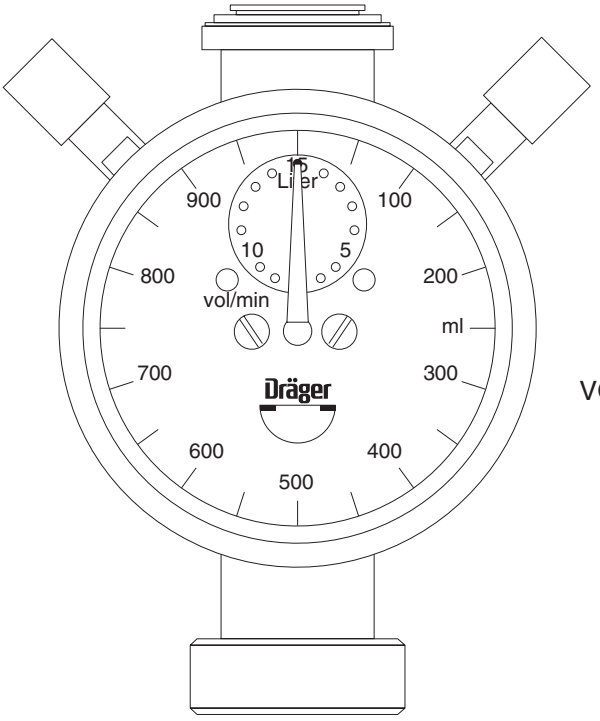
TEST EQUIPMENT AND FIXTURE ILLUSTRATIONS - Continued



TEST EQUIPMENT AND FIXTURE ILLUSTRATIONS - Continued

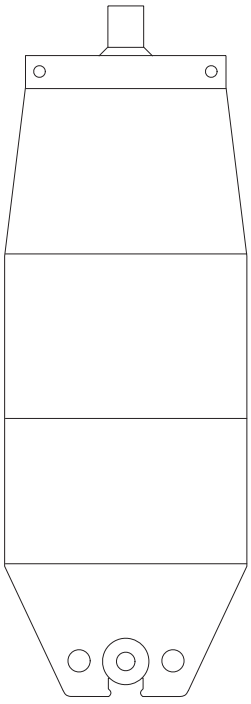
S000081
FLOW METER
TEST STAND



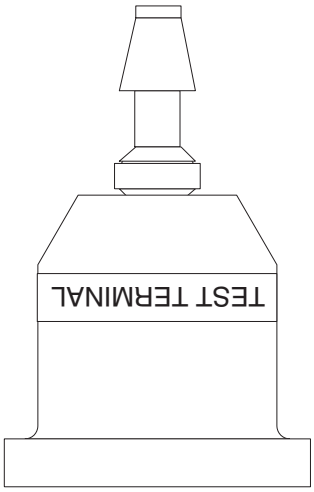


2212300
MINUTE
VOLUMETER

8401892
SIEMENS TEST LUNG



4104389
TEST TERMINAL
ADAPTER



SP18205

Periodic Manufacturer's Certification General Instructions

The purpose of these procedures is to provide detailed instructions for performing a Periodic Manufacturer's Certification (PMC) inspection on the Narkomed Mobile anesthesia machine.

A PMC consists of a complete Periodic Manufacturer's Service procedure and a certification level inspection based on Draeger Medical, Inc. Recommendations and equipment performance. Additional inspections are also performed to ensure proper product labeling.

Several additional documents have been created to assist the technician through the process. Following is a brief description of the purpose of each document.

Field Service Procedure:

Periodic Manufacturer's Certification Forms - Part Number SP00175.This procedure illustrates the sample checklists with typical periodic maintenance items filled in, including vapor concentration verification tests, parts replaced, general comments and certification levels. Also included are sample PMC labels marked to show several levels of certifications. An excerpt from Draeger Medical, Inc.'s *Anesthesia System Risk Analysis and Risk Reduction* is included, and also a sample of an Executive Summary to be furnished to the hospital's Risk Manager or Chief of Anesthesia.

Field Service Procedure:

DMI Recommendation Guidelines Index Anesthesia Systems - Part Number S010250.This Guideline was created to provide an assessment of each machine's certification. It contains various comprehensive overviews of possible equipment conditions and their associated certification levels.

The first list in the Recommendation Guidelines is a reference chart for machine certification based on equipment status. The second is an abbreviated summary of all DMI Recommendations and Failure Codes including the Condition Number, Equipment Condition, Recommended Corrections, Certification Code, and Tests Affected when applicable.

There is also a matrix classified as "Failure Codes" which identifies the correct manner in which to document equipment tests that fail, or were unable to be performed due to circumstances beyond the control of the service technician performing the inspection. (Ex: Air cylinder supply is unavailable to perform an Air High Pressure Leak test.) The Failure Codes section also indicates suggested resolution of the situation. Failure Code numbers begin at 34 and use the same certification levels strategy, and carry the same weight as NAD Recommendation equipment condition codes.

The final matrix is the most comprehensive index sorted by machine model and includes Equipment Condition, Certification Code, and DMI Recommendations. It also specifies any suggested upgrade path including ordering information that should be taken such as installing a Bellows with Pressure Limit Control 4109664-S01 Kit, after market modification kit to a machine not equipped with pressure limit control.

The letters A, B, C, D and the Roman Numerals I, II are used as codes in the individual matrix for each model of anesthesia machine. The letters A, B, C, and D are used in descending order to indicate the certification level of the equipment. They are as follows:

A = Certified

B = Certified with Recommendations

C = Conditionally Certified

D = No Certification

Roman Numerals I and II do not affect the certification level but rather are provided to give further instructions to the end user as follows:

I = The system in its present configuration shall only be used with a CO2 monitor incorporating an apnea warning. The operator of the system is advised to frequently scan the CO2 readings and alarm thresholds.

II =The present configuration of equipment requires that the unit operate at all times with an oxygen analyzer that includes a low oxygen warning. The operator of the system is advised to frequently scan the oxygen readings and alarm limits.

Following is an explanation of machine certification levels:

Certified- No DMI Recommendations or Failure Codes apply to machine being inspected. (Only item number 33 - "No Recommendations" shall apply for this certification level.)

Certified with Recommendations- A numbered DMI Recommendation or Failure Code with a code of B applies to the machine being examined.

Conditionally Certified- A numbered DMI Recommendation or Failure Code with a code of BCI or BCII applies to the machine being examined.

No Certification- A numbered DMI Recommendation or Failure Code with a code of D applies to the machine being examined.

When multiple recommendations apply, "No Certification" would take precedence over "Conditionally Certified" and "Certified with Recommendations". "Conditionally Certified" would take precedence over "Certified with Recommendations".

For example:

A **Narkomed 2B** could have DMI Recommendation number 21 and Failure Code 61.1 that apply. 21 - No ventilator pressure limit control. Code is B. 61.1 - Enflurane agent is unavailable to test. Code is BC. Correct certification for this machine is BC, which means CONDITIONALLY CERTIFIED WITH RECOMMENDATIONS.

A **Narkomed 4** could have DMI Recommendation numbers 14 and 21 apply.14 - CO2/Agent monitor exhaust port is not properly connected to the waste gas scavenger. Code B.

21 - No ventilator pressure limit control. Code B.The correct certification for this machine is B, which means “CERTIFIED WITH RECOMMENDATIONS”.

A **Narkomed 2B, 2C** or **GS** could have DMI Recommendation 30 apply.
30 - Anesthesia machine is equipped with inhalation anesthesia vaporizers without an agent analyzer in the breathing system. Code B. The correct certification for this machine is B, which means “CERTIFIED WITH RECOMMENDATIONS”.

A **Narkomed 6000** could have no DMI Recommendations or Failure Codes apply. The correct certification level for this machine is Code A, “CERTIFIED”.

The correct certification for this machine is A, which means "CERTIFIED".

Code, D also means "NO CERTIFICATION", also means the machine shall not receive a Periodic Manufacturer's Certification label. The machine shall receive a "WARNING - This System Is Not Certified" label, P/N 4114857. This label shall be placed at a prominent location on the right side of the machine after all other previous PM and "Vigilance Audit® Validation" labels have been removed.

PM Certification Procedure for Narkomed Mobile Anesthesia System

1. Use the PM Certification form for Narkomed Mobile Anesthesia Systems (P/N 4115597).
2. Completely fill in the header information.
3. All Narkomed Mobile machines are equipped with Humphrey valves. No “MJV-2 LUBRICATION” is needed to be performed for this type of anesthesia machine.
4. Replace the VENTILATOR RELIEF VALVE DIAPHRAGM every 12 months in accordance with SP00075. Place a check mark and the replacement date at “VENT VALVE REPLACEMENT” line on the Periodic Manufacturer’s Certification form.
5. If machine is equipped with a HALOTHANE Dräger Vapor 19 or 19.1 vaporizer, determine if vaporizer must be inspected for soil condition one. Check the serial number plate located on the rear of the vaporizer for a plus (+) preceding the serial number. A HALOTHANE vaporizer serial number not preceded with a (+) must be tested for soil in accordance with SP00073. If vaporizer does not need to be inspected, indicate so with a plus (+) next to the “Vapor Inspection (H)” line on the Vigilance Audit form. If vaporizer is soil condition 0, indicate so with “SOIL 0” written next to the “Vapor Inspection (H)” line on the Vigilance Audit form. If vaporizer is soil condition one, indicate so with “SOIL 1” written next to the “Vapor Inspection (H)” line on the Vigilance Audit form. Place a “CAUTION DO NOT USE” label (part # 4114327) on the vaporizer, and issue a departmental alert. The TSR shall also seek permission from the equipment operator to remove the failed vaporizer from the machine and apply a replacement vaporizer or an adapter block onto the mount. All “SOIL 1” vaporizers must be removed from service for machine to receive certification.
6. Perform the vapor concentration test on all Dräger vapor vaporizers in accordance with SP00073 at a six month maximum interval. Perform the vaporizer concentration test on all Desflurane vaporizers in accordance with SP00091 for fixed mount vaporizers and SP00189 for user removable D-tec vaporizers at a six month maximum interval. For every vaporizer tested, fill out a "VAPOR VAPORIZER CALIBRATION CHECK" label (part # S010016). Information on this label shall include your signature, type of agent, date tested, a No Agent To Test or the test results @ 1%, 2.5%, 4% for H, E, I, or S vaporizers, or @ 4%, 10%, 12%, 16% for Desflurane vaporizers, and a PASS or FAIL indication. This label shall be attached to the upper right side of the vaporizer. If vaporizer fails the concentration verification, internal leak, or exclusion system tests, check "NO" in the "RECOMMENDED FOR USE" section on the PM Certification form. Place a "CAUTION DO NOT USE" label (part # 4114327) on the vaporizer, and issue a departmental alert. The TSR shall also seek permission from the customer to remove the failed vaporizer from the machine and install a replacement vaporizer or an adapter block onto the mount. All nonfunctional vaporizers must be removed from service for machine to receive certification.

7. Proceed with PM Certification procedure. If any tests fail refer to the "Failure Codes" listing in DMI Recommendations Guidelines Index (P/N S010250) to determine correct certification level starting point. Failure codes shall be documented on the "RECOMMENDATIONS / GENERAL COMMENTS" section of the PM Certification form and on the Executive Summary. If a test fails that has not been identified by the "Failure Codes" list, consult with Draeger Medical, Inc. to assess the proper certification level.
8. Based on the "EQUIPMENT CONDITION" inspect the machine for any "DMI RECOMMENDATIONS" that would apply. Use the Narkomed Mobile section of the "RECOMMENDATION GUIDELINES INDEX" (P/N S010250). Note all applicable DMI recommendations on the Executive Summary. NOTE: If using a carbon form, indicate the Equipment Condition number and to see reverse side under the "RECOMMENDATIONS / GENERAL COMMENTS" section of the form.
9. Determine the correct certification level of the machine based on the combined lowest common denominator of "Equipment Conditions" and "Failure Codes". If the machine is at least conditionally certified fill out the "PM CERTIFICATION" label. Check the box(s) on the validation label where appropriate. Write the month and year, (three months from date of PM Certification) next to "NEXT VISIT DUE:". If certification level is "D", machine shall not receive a "PM CERTIFICATION" label. Any machine not receiving a PM Certification label shall receive a "WARNING NOT CERTIFIED" label, P/N 4114857. This label shall be placed at a prominent location on the left side of the machine after all other previous PMS and Vigilance Audit Validation labels have been removed.
10. In the "CERTIFICATION LEVEL" section of the PM Certification form, record the last visit certification level, the current certification level and the next visit due month and year, (three months from date of PM Certification) in the spaces provided.
11. If applicable, remove the previous PM CERTIFICATION VALIDATION label and attach the new label (P/N S010006 w/phone #, or S010007 w/o phone #) in a prominent location on the rear of the anesthesia machine.
12. Check the appropriate boxes on the "PM CERTIFICATION NOTICE" label, (part # S010011). If the machine is not certified, the last box of this notice label shall be marked. Attach this notice near the flowmeter shield of the anesthesia machine.
13. Have the customer sign each PM Certification form or the Executive Summary, and review any Failure Codes equipment conditions and DMI Recommendations with the customer.
14. Return top copy to Draeger Medical, Inc. Service Department, keep middle copy for service organization records, give bottom copy to customer.

(✓) **6.1 SELF-DIAGNOSTICS**

6.1.1 Turn the System Power switch to ON and verify the "ON" LED is lighted?

6.1.2 Verify all LED's on the keypad and ventilator displays are lit.

6.1.3 Verify that the following is displayed on the Display:

NARKOMED
COPYRIGHT 1997-1998 NAD. INC.
VERSION X.XX NARKOMED
SOFTWARE ID: XXXX

FIRMWARE	PASS
RAM	PASS
VIDEO	PASS
A/D CONVERTER	PASS
AUDIO - PRIMARY	PASS
BACKUP	PASS
SERIAL I/O	PASS
CLOCK	PASS
NON-VOLATILE MEMORY	PASS
FUNCTIONAL	

(✓) 6.1.4 Record the machine software version on the header of the checklist form.

6.2 ELECTRICAL SAFETY- One Year Service Interval; Due Date _____

(✓) 6.2.1 Battery Check & Ground Continuity

6.2.1.1 Unplug the AC power cord for all devices mounted to the machine that may provide an alternate path to earth ground, such as a Desflurane vaporizer.

6.2.1.2 Unplug the machine's AC power cord and plug the power cord of the safety analyzer into this AC receptacle.

NOTE: Do not plug the safety analyzer power cord into a line isolation monitor circuit, as inaccurate readings may occur.

NOTE: The BIOTECH 501 PRO will automatically test the source outlet for open ground (or ground resistance of 31 Ohms or higher), reverse polarity, open neutral and open line. (The latter two conditions will prevent the analyzer from powering up.)

6.2.1.3 Is the green "AC POWER" LED off? __ (Y)

6.2.1.4 Does the "AC PWR FAIL" message appear in the Advisory display? __ (Y)

6.2.1.5 Press and hold the "BATTERY TEST" button.

6.2.1.6 Is green Battery Test LED lighted? __ (Y)

6.2.1.7 Release the "BATTERY TEST" button.

6.2.1.8 Turn on the safety analyzer and configure it to measure “Resistance” according to the manufacturers documentation. Attach a test lead to the “SINGLE LEAD” connector of the analyzer. Connect the other end of the test lead to the AC receptacle ground socket on the safety analyzer. Verify a displayed resistance of 0.00 ohms or, if necessary, calibrate the unit according to manufacturers documentation.

6.2.1.9 Plug the machine’s AC power cord into the safety analyzer.

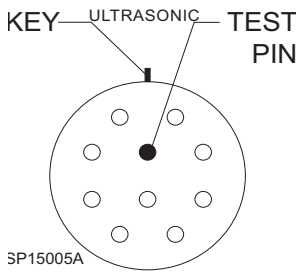
6.2.1.10 Apply the analyzer’s test lead to a cylinder yoke bolt.

6.2.1.11 What is the value displayed on the safety analyzer? ___ ohm (0-0.1)

(✓) 6.2.2 Circuit Isolation

6.2.2.1 Disconnect the respiratory volume sensor cord from the interface panel.

6.2.2.2 Using a multimeter set to its highest resistance range apply the test leads between the yoke bolt and circuit common at the volume interface test pin. Use the position indicated on the illustration for the ultrasonic flow sensor connector. There shall be no continuity between these two points.



6.2.2.3 Reconnect the respiratory volume sensor cord to the interface panel.

6.2.3 Chassis Leakage Current

6.2.3.1 Apply the analyzer test lead to a cylinder yoke bolt.

6.2.3.2 Configure the safety analyzer to the measure “CHASSIS LEAKAGE CURRENT” according to the manufacturers documentation.

6.2.3.3 Record the total leakage current with the Polarity and Ground switches set as follows:

		Ground	Polarity
(✓)	6.2.3.3.1	Normal	Normal
(✓)	6.2.3.3.2	Open	Normal
(✓)	6.2.3.3.3	Open	Reversed
(✓)	6.2.3.3.4	Normal	Reversed

6.2.3.4 Verify that the leakage current is 100* microamps or less in each of the switch positions (110 microamps or less for the 220/240 volt power supply option).

6.2.3.5 300 microamps if external monitors are plugged into convenience receptacles.

6.2.3.6 Shut off and unplug the safety analyzer. Remove the anesthesia machine plug from the analyzer and plug it back into the original AC receptacle.

(✓) **6.3 CONFIGURATION**

6.3.1 Press the CONFIG key.

6.3.2 The CONFIGURE screen is displayed.

6.3.3 Verify the correct Time and Date.

6.3.4 Press the exit key to exit the function.

6.4 SERVICE DATA

6.4.1 Press and hold the Oxygen High Limit key and the Volume Low Limit key, and then press the UP ARROW key.

6.4.2 The Main Service Screen shall appear.

6.4.3 Select and enter the Service Log.

6.4.4 Verify any pertinent information from the Service Log. Contact the Draeger Medical, Inc. Technical Service Department if necessary.

6.4.5 Press EXIT to return to the Main Service screen.

6.4.6 Using the arrow keys, select the SRVC Service Code.

6.4.7 Press the SELECT key and enter your Technical Service Rep. I.D. number.

(✓) 6.4.8 Press the RESET key. This resets the last service date to the current date and resets the hours run since last service to zero.

6.4.9 Press the PMS SCHED key.

(✓) 6.4.10 Select and enter the month of the next service due date.

NOTE: The internal clock of the machine limits the amount of date advance to a maximum of six months from the current service date.

6.4.11 Press the EXIT key to return the main service screen. If not performing monitor calibrations, press the EXIT key again to return to normal operation mode.

6.5 CALIBRATIONS - One Year Service Interval; Due Date _____

6.5.1 To bring up the Oxygen Monitor Service Screen, press the Mon Cal key.

6.5.2 Remove the Oxygen sensor from the Breathing Pressure Hose Assembly, and remove the Oxygen Sensor capsule from the Oxygen Sensor Housing.

(✓) 6.5.3 When the CURRENT CELL A and CURRENT CELL B readings have stabilized, press the ZERO key and verify that the new offset values are stored.

NOTE: The higher the offset, the higher the calculated O_2 concentration appears at high concentrations.

6.5.4 Put the Oxygen Sensor capsule into the Oxygen Sensor Housing.

6.5.5 Press the PRES MON key.

6.5.6 Remove Breathing Pressure Hose Assembly from Inspiratory Valve dome to expose the Breathing Pressure Sensor line to ambient pressure.

6.5.7 Let the Current Pressure Value stabilize and press the ZERO key to store the value.

6.5.8 Remove Breathing Pressure Sensor line from the machine.

6.5.9 Connect a Pressure Monitor Adapter, (P/N 4115043) and calibrated manometer to the Breathing Pressure quik connect on the machine monitor interface.

NOTE: Zero manometer prior to connecting to monitor interface. Slight pressure will be noticed on manometer when connected to monitor interface, DO NOT re-zero manometer.

6.5.10 Pressurize the circuit to 50 cm H_2O and allow the [Current Value] to stabilize.

(✓) 6.5.11 Press the SPAN key and verify that the new span values are stored.

6.5.12 Release the pressure, disconnect the manometer and test fixture, reconnect the Breathing Pressure Sensor line to the quik connect on the machine monitor interface and insert the Breathing Pressure Hose Assembly into Inspiratory Valve dome.

6.5.13 Press EXIT to return to the Main Service screen.

6.5.14 Press EXIT to return to normal operation.

(✓) 6.6 ABSORBER INSPECTION

Absorber System Inspection and Maintenance

6.6.1 Remove the O_2 Sensor Housing and/or Oxygen Sensor Plug and Breathing Pressure Hose Assembly from the inspiratory valve dome and examine the O-rings on each assembly. Replace O-rings as necessary.

6.6.2 Remove the Inspiratory and the Expiratory valve domes.

6.6.3 Are any pins on the valve crater damaged? Inspiratory ___ (N) Expiratory ___ (N) Replace complete valves as necessary.

6.6.4 Are any pins on the valve domes damaged? Inspiratory ___ (N) Expiratory ___ (N) Replace complete valves as necessary.

6.6.5 Is the valve disc in good condition? Inspiratory ___ (Y) Expiratory ___ (Y) Replace as necessary.

6.6.6 Are the valve dome washers in good condition? ___ (Y) Replace washers as necessary.

6.6.7 Reinstall the Inspiratory and Expiratory valve domes.

(✓) **6.6.8 Ultrasonic Flow Sensor**

6.6.8.1 Remove the Ultrasonic Flow Sensor connector hose.

6.6.8.2 Are the connector hose, connector, and O-ring components in good condition? ___ (Y) Replace components as necessary.

6.6.8.3 Remove the Expiratory valve.

6.6.8.4 Is the washer under the valve in good condition? ___ (Y) Replace washer as necessary.

6.6.8.5 Remove the PEEP valve.

6.6.8.6 Is the washer under the PEEP valve in good condition? ____(Y) Replace washer as necessary.

6.6.8.7 Reattach the PEEP valve.

6.6.8.8 Reattach the Expiratory valve.

6.6.8.9 Remove the Ultrasonic Flow Sensor from the mounting bracket

6.6.8.10 Remove the flow housing/transducer assembly from the electronics housing.

6.6.8.11 Remove both transducers from the flow housing; examine each O-ring and condition of all components, replace O-rings as necessary, then reassemble the Ultrasonic Flow Sensor.

6.6.8.12 Reattach the Ultrasonic Flow Sensor to the mounting bracket.

6.6.8.13 Reattach the connector hose between the Ultrasonic Flow Sensor and Expiratory valve.

(✓) **6.7 HIGH PRESSURE LEAK**

NOTE: Minimum cylinder pressures required for High Pressure Leak tests are:

N2O: 600 psi;

O2, Air: 1000 psi.

6.7.1 Turn the machine to Standby.

6.7.2 Verify the Auxiliary Oxygen flow control valve is closed

6.7.3 Disconnect all pipeline supply hoses at the wall outlets.

6.7.4 Open then close and remove each cylinder. And if applicable remove the yoke plug from each additional yoke assembly.

6.7.5 Note the reading on each of the cylinder pressure gauges and start a stop watch.

6.7.6 Are there two (2) yoke index pins installed securely in each yoke? ___(Y)

6.7.7 Is the proper gas I.D. label affixed to each yoke? ___ (Y)

6.7.8 After two (2) minutes, is the pressure loss equal to or less than 50 PSI? ___(Y)

6.7.9 Verify the presence of only one (1) cylinder washer, then reattach and secure the cylinders to each yoke assembly, then open each cylinder valve.

6.8 BREATHING SYSTEM

6.8.1 Absorber & Freshgas Leak/ Vaporizer Leak

6.8.1.1 Close all flow control valves.

6.8.1.2 Set the AUTO/BAG selector to BAG.

6.8.1.3 Close the APL valve.

6.8.1.4 Interconnect the Inspiratory valve and expiratory port on the Ultrasonic Flow Sensor with a 22 mm hose (P/N 9995132).

6.8.1.5 Attach a Freshgas Leak Test Adapter (P/N 4115041), Test Terminal Adapter (P/N 4104389), and Digital Pressure Manometer to the bag mount.

6.8.1.6 Apply 50 cm H_2O test pressure to the absorber system and start a stop watch.

6.8.1.7 Is the pressure on the manometer within 49 to 51 cm H_2O? ___ (Y)

6.8.1.8 Is the pressure displayed on the Breathing Pressure Gauge +/- 3 cm H_2O of the value displayed on the test manometer?___(Y)

(✓) 6.8.1.9 After thirty (30) seconds, is the pressure displayed on the manometer equal to or greater than 40 cm H_2O? ___(Y)

6.8.1.10 If applicable, turn on the vaporizer to the first graduated marking. Reapply 50 cm H_2O of pressure to the system and start a stopwatch.

(✓) 6.8.1.11 After thirty (30) seconds, is the vaporizer test pressure displayed on the manometer equal to or greater than 40 cm H_2O? ___(Y). Turn off the vaporizer.

(✓) 6.8.2 APL Valve

6.8.2.1 Open the APL valve to its stop.

6.8.2.2 Verify Scavenger is active.

6.8.2.3 Turn the System Power switch to ON.

6.8.2.4 Set the Oxygen flow to 8 l/min.

6.8.2.5 Is the test pressure within 0 to 3 cm H_2O? ___ (Y)

6.8.2.6 Remove Freshgas Leak Test Adapter (P/N 4115041), Test Terminal Adapter (P/N 4104389), and Digital Pressure Manometer (P/N PDM 200CD) from the bag mount.

(✓) 6.8.3 O_2 Flush

6.8.3.1 Attach a 33 mm x 22 Female Adapter (P/N 4115087) to the top port of the test volumeter.

6.8.3.2 Remove the ventilator hose from the absorber and bellows, and connect to the Bag Mount terminal.

6.8.3.3 Connect test volumeter to the end of ventilator hose.

6.8.3.4 Close the APL valve.

6.8.3.5 Press and hold the O_2 FLUSH button for 6 seconds; multiply the value obtained by 10.

6.8.3.6 Is the calculated Oxygen flush flow rate within 45 to 65 l/min.? ___ (Y)

6.8.3.7 After releasing the flush, does the flow of Oxygen stop immediately? ___ (Y)

6.8.3.8 Reattach ventilator hose between absorber and bellows ventilator terminals.

6.8.3.9 Remove all test equipment. Remove 22mm hose from Inspiratory valve and expiratory port on the Ultrasonic Flow Sensor.

(✓) 6.8.4 Expiratory Valve Leak

6.8.4.1 Connect a 22 mm hose (P/N 9995132) between the Inspiratory valve and the bag mount.

6.8.4.2 Connect a test terminal (P/N 4104389) to the expiratory port on the Ultrasonic Flow Sensor.

6.8.4.3 Connect a 0-250 ml/min. flowmeter (P/N S000081) to the test terminal.

6.8.4.4 Turn up the Oxygen flow until the system pressurizes to 30 cm H_2O. Adjust the APL valve as necessary to maintain 30 cm H_2O.

6.8.4.5 Is the value indicated on the flowmeter within 0 to 60 ml/min.? ___ (Y)

6.8.4.6 Turn off O_2 flow. Fully close APL valve.

6.8.4.7 Remove all test equipment.

(✓) 6.8.5 Inspiratory Valve Leak

6.8.5.1 Turn the System Power switch to Standby.

6.8.5.2 Connect a test terminal (P/N 4104389) to the Inspiratory valve.

6.8.5.3 Connect a Fresh Gas Leak Adapter (P/N 4115041) and manometer to the test terminal on the Inspiratory valve.

6.8.5.4 Connect another test terminal to the bag mount.

6.8.5.5 Connect a 0-250 ml/min. flowmeter (S000081) to the test terminal on the bag mount.

6.8.5.6 Pressurize the test circuit to 30 cm H_2O.

6.8.5.7 Is the value indicated on the flowmeter within 0 to 60 ml/min.? ___ (Y)

6.8.5.8 Turn the system power switch to ON.

6.8.5.9 Remove all test equipment.

(✓) 6.8.6 Absorber PEEP Valve

6.8.6.1 Open the APL valve.

6.8.6.2 Disconnect the pressure line going to the Breathing Pressure gauge and connect to a test manometer.

6.8.6.3 Connect a Fresh Gas Outlet Volume Test Device (S010158) to the Fresh gas outlet.

6.8.6.4 Install a test breathing circuit or disposable breathing circuit onto the Inspiratory and Expiratory valves of the absorber.

6.8.6.5 Connect the test terminal, of the Fresh Gas Outlet Volume Test Device, to the Y-piece of the breathing circuit.

6.8.6.6 Set the O_2 flow to 5 l/min.

6.8.6.7 Adjust the absorber PEEP valve clockwise to the maximum position.

6.8.6.8 Does the PEEP valve adjust smoothly? ___ (Y)

6.8.6.9 Is the maximum PEEP indicated on the test gauge greater than 15 cm H_2O? ___ (Y)

6.8.6.10 Adjust the absorber PEEP valve counterclockwise to its minimum position.

6.8.6.11 Is the PEEP indicated on the test gauge less than or equal to 3 cm H_2O? ___(Y)

6.8.6.12 Close the O_2 flow control valve.

6.8.6.13 Remove the test equipment and reconnect the pressure line to the Breathing Pressure gauge.

6.9 OXYGEN ANALYZER

6.9.1 Press the Cal key.

NOTE: Ensure that the sensor has stabilized in ambient air for several minutes.

(✓) 6.9.2 After calibration is completed, is the O_2 concentration 21%? ___ (Y)

6.9.3 The warning message INSP O_2 LOW shall appear on the central alarm display, and an audible alarm shall sound.

6.9.4 Press the ALARM SILENCE key and verify the audio alarm is silenced.

6.9.5 Remove the Breathing Pressure Hose Assembly from the Inspiratory valve dome.

6.9.6 Place the Oxygen Sensor housing directly into the Inspiratory valve dome.

6.9.7 Verify the AUTO/BAG selector is set to BAG.

6.9.8 Close the APL valve.

6.9.9 Attach a 22 mm hose (P/N 9995132) to the Inspiratory valve.

6.9.10 Attach a Breathing System Leak Test Device (P/N S010159) to the bag mount.

6.9.11 Press the O2 Flush.

6.9.12 After 20 seconds, is the O2 concentration within 90 to 100 %? ___ (Y)

6.9.13 Release the O2 Flush, does the flow cease immediately? ___ (Y)

6.9.14 Set the Oxygen flow to 8 l/min.

(✓) 6.9.15 After 1 minute, is the O2 concentration within 97 to 100 %? ___ (Y)

6.10 FLOWMETERS & CONCENTRATIONS

(✓) 6.10.1 Oxygen Flowmeter

6.10.1.1 Is it possible to adjust the flow of Oxygen over the full range of the flowmeters? ___ (Y)

6.10.1.2 Set the Oxygen flow to 4 l/min.

6.10.1.3 Is the correct flow control knob and label attached to the Oxygen flow control valve? ___ (Y)

(✓) 6.10.2 Air Flowmeter

6.10.2.1 If not configured with an Air Cylinder yoke, attach the Air Pipeline hose.

6.10.2.2 Is it possible to adjust the flow of the Air over the full range of the flowmeter? ___ (Y)

6.10.2.3 Set the Air flow to 2 l/min.

6.10.2.4 After the value stabilizes, is the O2 concentration within 71 to 77 %? ___ (Y)

6.10.2.5 Close the Air flow control valve.

6.10.2.6 Is the correct flow control knob and label attached to the Air flow control valve? ___ (Y)

6.10.3 Nitrous Oxide Flowmeter

6.10.3.1 Set the Nitrous Oxide flow to 2 l/min.

6.10.3.2 After the value stabilizes, is the O2 concentration within 64 to 70 %? ___ (Y)

6.10.3.3 Is the correct flow control knob and label attached to the Nitrous Oxide flow control valve? ___ (Y)

6.10.3.4 Is it possible to adjust the flow of nitrous oxide over the full range of the flowmeter? ___ (Y)

(✓) 6.10.4 Oxygen Ratio Control

6.10.4.1 Open the Nitrous Oxide flow control valve to the stop position.

6.10.4.2 After the value stabilizes, is the O_2 concentration within 21 to 29 %? ___ (Y)

6.10.4.3 Set the Oxygen flow to 2 l/min.

6.10.4.4 After the value stabilizes, is the O_2 concentration within 21 to 29 %? ___ (Y)

6.10.4.5 Set the Oxygen flow to 1 l/min.

6.10.4.6 After the value stabilizes, is the O_2 concentration within 21 to 29 %? ___ (Y)

6.10.4.7 Close the Oxygen flow control valve.

6.10.4.8 Close the Nitrous Oxide flow control valve.

(✓) 6.10.5 Auxiliary Oxygen Flowmeter

6.10.5.1 Connect a test manometer to the Auxiliary Oxygen outlet using a PDM/Suction adapter (P/N 4115038).

6.10.5.2 Slowly open flowmeter valve until a pressure of 50 cm H_2O is achieved.

6.10.5.3 Close flowmeter valve.

6.10.5.4 After 10 seconds, is the pressure within 40 to 60 cm H_2O? ___ (Y)

6.10.5.5 Remove the test manometer and adapter.

6.10.5.6 Is it possible to adjust the Auxiliary Oxygen flowmeter over the full range of the flowmeter? ___(Y)

6.10.5.7 Set the Auxiliary O_2 flow rate to 5 L/min.

6.10.5.8 Hold the Oxygen sensor at the Auxiliary Oxygen flowmeter outlet.

6.10.5.9 After the value stabilizes, is the O_2 concentration within 80 to 100 %? ___ (Y)

6.10.5.10 Reinstall the Breathing Pressure Hose Assembly.

6.10.5.11 Insert the Oxygen sensor into the Breathing Pressure Hose Assembly.

6.10.5.12 Close the Auxiliary Oxygen flow control valve.

6.11 HIGH PRESSURE REGULATORS – Six Month Service Interval; Due Date _____

(✓) 6.11.1 N2O Regulator- if applicable

NOTE: Minimum cylinder pressure for N2O regulator test is 600 psi.

6.11.1.1 Configure the test gauge (P/N 4114807) using a N2O nut/stem DISS connector (P/N 4114830-004) on the hose, and N2O DISS body connector (P/N 4114830-003) on the valve body side. If the machine is configured with CSA style fittings reverse the position of the connectors.

6.11.1.2 Connect the test fixture hose to the machine's Nitrous Oxide pipeline inlet.

6.11.1.3 Connect the Nitrous Oxide pipeline supply hose to the test fixture.

6.11.1.4 Open the Nitrous Oxide and the Oxygen cylinder valves.

6.11.1.5 Set the Oxygen and Nitrous Oxide flows to 4 l/min.

6.11.1.6 Depress the push button on the test device.

6.11.1.7 Release the push button. After the pressure decay stabilizes, is the regulator output pressure within 40 to 49 psi? ___ (Y)

6.11.1.8 Remove the test fixture.

NOTE: If a pressure decrease does not occur, either the hospital's supply pressure is too low or the regulator pressure is set too high.

(✓) 6.11.2 O_2 Regulator

NOTE: Minimum cylinder pressure for O_2 regulator test is 1000 psi.

6.11.2.1 Configure a test gauge (P/N 4114807) using an O_2 nut/stem DISS connector (P/N 4114830-006) on the hose and an O_2 DISS body connector (P/N 4114830-005) on the valve body side. If the machine is configured with CSA style fittings reverse the position of the connectors.

6.11.2.2 Connect the test fixture hose to the machine's Oxygen pipeline inlet.

6.11.2.3 Connect the Oxygen pipeline supply hose to the test fixture.

6.11.2.4 Set the Oxygen flow to 4 l/min.

6.11.2.5 Depress the push button on the test device.

6.11.2.6 Release the push button. After the pressure decay stabilizes, is the regulator output pressure within tolerance given in the following table? ___ (Y)

NOTE: If a pressure decrease does not occur, either the hospital's supply pressure is too low or the regulator pressure is set too high.

Cylinder Pressure psi	USA Compensated Regulator output tolerances	CSA Compensated Regulator output tolerances
2000	38 to 44	41 to 47
1800	39 to 45	42 to 48
1600	40 to 46	43 to 49
1400	41 to 47	44 to 50
1200	42 to 48	45 to 51
1000	43 to 49	46 to 52

(✓) **6.12 LOW O2 SUPPLY – Six Month Service Interval; Due Date _____**

6.12.0.1 Close the Oxygen Cylinder valve and drain Oxygen cylinder pressure.

6.12.0.2 Depress the push button on the test device.

6.12.0.3 Adjust the Oxygen flow to 500 ml/min.

6.12.0.4 Release the test device push button.

6.12.0.5 Is the pressure on the test gauge when the LO O2 SUPPLY message appears on the monitor within 34 to 40 psi? ___ (Y)

6.12.0.6 Close O2 Flow control valve.

6.12.0.7 Remove the test equipment.

6.13 OXYGEN SUPPLY FAILURE PROTECTION

6.13.1 Connect all pipeline supplies.

(✓) 6.13.2 *Is the flow of Oxygen 150 to 200 ml/min.? ___ (Y)

6.13.3 Open the Nitrous Oxide flow control valve.

(✓) 6.13.4 *Is the flow of Nitrous Oxide within 375-750 ml/min.? ___ (Y)

6.13.5 Adjust the Oxygen, Nitrous Oxide and AIR gases to 4 l/min.

6.13.6 Disconnect the Oxygen pipeline supply and close the Oxygen cylinder valve.

(✓) 6.13.7 Do all fresh gas flows cease when the Oxygen pressure is depleted? ___(Y)

6.13.8 Reconnect the Oxygen pipeline supply.

6.13.9 Close all cylinder valves and then disconnect the Nitrous Oxide pipeline supply.

6.13.10 Drain the cylinder contents then reconnect the pipeline supplies.

6.13.11 Close all flow control valves.

* Nitrous Oxide Bypass flow and Minimum Oxygen flow specifications are given @ 50 psi. Pipeline pressure deviations may affect these tests.

6.14 PRESSURE MONITOR

6.14.1 Disconnect the Breathing Pressure Sensor line from the Breathing Pressure interface on the machine.

6.14.2 Connect a PDM to Monitor Adapter (P/N 4115043) and test manometer to the Breathing Pressure interface on the machine.

6.14.3 Adjust the test pressure to 0 cm H_2O.

6.14.4 Simultaneously turn “ON” the ventilator and start a stopwatch.

(✓) 6.14.5 Does the APNEA PRESSURE alarm appear on the alarm display as a CAUTION within 13 to 17 seconds? ___ (Y)

(✓) 6.14.6 Increase the test pressure slowly. Does the APNEA PRESSURE alarm deactivate within 10 to 14 cm H_2O? ___ (Y)

6.14.7 First decrease the pressure then increase the test pressure above the threshold line shown on the display, and begin timing with a stopwatch.

(✓) 6.14.8 Does the CONTINUOUS PRES alarm appear as a warning within 13 to 17 seconds? ___ (Y)

(✓) 6.14.9 Decrease the pressure slowly. Does the CONTINUOUS PRES alarm deactivate within 10 to 14 cm H_2O? ___ (Y)

(✓) 6.14.10 Increase the test pressure slowly. Does a VENT PRESS HI alarm activate as a warning alarm within 47 to 53 cm H_2O? ___ (Y)

(✓) 6.14.11 Increase the sub-atmospheric test pressure slowly. Does the SUB ATM PRES warning alarm activate within –7 to –13 cm H_2O? ___ (Y)

6.14.12 Turn the ventilator "OFF".

6.14.13 Open APL valve.

6.14.14 Remove the test equipment and reconnect the Breathing Pressure Sensor line to the Breathing Pressure interface on the machine.

6.15 VENTILATOR

NOTE: Readjustment of inspiratory flow to limit the inspiratory plateau may be required to reduce erratic tidal volumes and breath rates caused by artifact volumes.

6.15.1 Remove the bellows vent hose and the scavenger hose at the ventilator relief valve. Remove the bellows sub-assembly and remove bellows.

6.15.2 Visually inspect the bellows for deterioration particularly at it's seems and corrugations. Replace as necessary.

6.15.3 Verify the presence and condition of it's sealing O-ring. Replace as necessary. Reassemble all components.

6.15.4 Set O_2/AIR mode switch to "O_2".

6.15.5 Turn the ventilator "ON".

6.15.6 Set the FREQUENCY to 10 BPM.

(✓) 6.15.7 Press and hold the EXTENDED RANGE switch and set the I:E ratio to 2:1. Using a stopwatch, time the extended I:E ratio. Is the inspiratory time within 3.6 to 4.4 seconds and the expiratory time within 1.8 to 2.2 seconds? ___ (Y)

(✓) 6.15.8 Set the I:E RATIO to 1:2. Using a stopwatch, time the I:E ratio. Is the inspiratory time within 1.8 to 2.2 seconds and the expiratory time within 3.6 to 4.4 seconds? ___ (Y)

6.15.9 Adjust the Oxygen flow to 500 ml/min.

6.15.10 Set the Tidal Volume to 1200.

6.15.11 Attach a patient circuit to the absorber system.

6.15.12 Set the pressure limit control to MAX.

6.15.13 Adjust the Inspiratory Flow to the bottom of the LOW zone.

6.15.14 Occlude the Y-piece.

6.15.15 Press the O_2 Flush momentarily to inflate the bellows.

6.15.16 Adjust the Inspiratory Flow until a peak pressure of 80 cm H_2O is achieved.

(✓) 6.15.17 Set the Pressure Limit Control to within the 30 range. Readjust within the band as necessary to achieve proper value, is the peak pressure at the 30 range within 27 to 33 cm H_2O? ___ (Y)

(✓) 6.15.18 Set the Pressure Limit Control to the MIN position. Is the peak pressure at the MIN range within 0 to 15 cm H_2O? ___ (Y) Return the Pressure Limit control to MAX.

6.15.19 Disconnect the hose between the expiratory valve and the ultrasonic flow sensor and blow into it.

(✓) 6.15.20 Does the Reverse Flow message appear on the display? ___ (Y)

6.15.21 Reconnect the hose between the expiratory valve and the flow sensor.

6.15.22 Insert a test minute volumeter between the exhalation valve and PEEP valve.

6.15.23 Open the Y-piece.

6.15.24 Turn the ventilator off and press the ALL STBY key to clear alarms.

6.15.25 Turn the ventilator “ON” and start a stop watch.

6.15.26 Does APNEA-VOLUME appear as a Caution within 13 to 17 seconds? ___ (Y)

6.15.27 Attach a 3 liter breathing bag to the Y-piece.

NOTE: Bag should be placed on a flat horizontal surface to reduce artifact volume.

6.15.28 Press the O2 Flush momentarily to inflate the bellows.

6.15.29 Set the Inspiratory Flow to the MED and readjust as necessary to fully collapse the bellows.

(✓) 6.15.30 Observe the operation of each unidirectional valve disc at eye level and make sure the inspiratory valve disc raises only during the inspiration phase, and the expiratory valve raises only during the exhalation phase.

(✓) 6.15.31 Is the tidal volume on the volume monitor and on the test volumeter within 20 % of each other? ___ (Y)

6.15.32 Does the volume monitor display 10 BPM? ___ (Y)

6.15.33 Does the display correctly track the Breathing Pressure waveform? ___ (Y)

6.15.34 Verify AIR pipeline hose is connected.

(✓) 6.15.35 Set O2/AIR mode switch to "AIR". Does ventilator continue to cycle properly. ___(Y)

6.15.36 Set O2/AIR mode switch back to "O2".

6.16 BELLOWS ADULT

(✓) 6.16.1 What is the tidal volume indicated on the test volumeter within 960 to 1440 ml? ___ (Y)

(✓) 6.16.2 Does the bellows remain fully inflated during the expiratory pause phase? ___ (Y)

6.16.3 Remove the ventilator hose from the bellows hose terminal.

6.16.4 Attach a test terminal to the bellows hose terminal.

6.16.5 Connect a 0-250 ml/min. flowmeter (P/N S000081) to the test terminal.

6.16.6 Set the FREQUENCY to 1 BPM.

(✓) 6.16.7 Is the drive gas leakage indicated during the inspiratory phase within 0 to 50 ml/min.? ___ (Y)

6.16.8 Remove the test equipment from the ventilator hose terminal and reconnect the ventilator hose to the bellows ventilator hose terminal.

6.16.9 Set the FREQUENCY to 10 BPM.

6.16.10 Adjust the O2 flow to 8 l/min.

6.16.11 Adjust the Tidal Volume to maximum.

6.16.12 Press the O_2 Flush momentarily to inflate the bellows.

6.16.13 Adjust the INSPIRATORY FLOW to fully compress the bellows.

(✓) 6.16.14 Is the Tidal Volume on the test volumeter greater than or equal to 1400 ml? ___(Y)

(✓) 6.16.15 Is the PEEP value displayed on the monitor within 0 to 3 cm H_2O? ___ (Y)

6.16.16 Remove the breathing bag from the Y-piece and replace it with a test lung.

6.16.17 Adjust the O_2 flow to 300 ml/min.

6.16.18 Adjust the Tidal Volume to 200 ml.

6.16.19 Does the bellows stop adjust smoothly and engage properly? ___ (Y)

6.16.20 Adjust the INSPIRATORY FLOW to fully compress the bellows.

(✓) 6.16.21 Is the Tidal Volume on the test volumeter within 125 to 250 ml? ___ (Y)

6.16.22 Close the Oxygen flow control valve.

6.16.23 Remove the test lung and set the AUTO/BAG selector to BAG.

6.16.24 Press the Alarms All Standby key.

6.17 SCAVENGER- Six Month Service Interval; Due Date _____

NOTE: If the ambient air in the local environment contains a significant amount of dust and lint, the cleaning frequency must be increased to compensate for these conditions.

(✓) 6.17.1 Scavenger - Passive Mode

6.17.1.1 Remove the scavenger hoses and drain all accumulated moisture. Inspect all scavenger hoses for deterioration and replace as necessary. Reinstall hoses and bag.

6.17.1.2 Ensure that the suction needle valve (not used in passive mode) is closed.

6.17.1.3 Positive Pressure Test:

6.17.1.3.1 Connect a 19mm scavenger hose between the Vent Relief valve and the top port of the scavenger. Connect another 19 mm scavenger hose between APL valve and the second scavenger port.

6.17.1.3.2 Interconnect the inspiratory valve and expiratory valve or expiratory port on the ultrasonic flow sensor, if applicable with a 22 mm hose (P/N 9995132).

6.17.1.3.3 Set Man/Auto valve to “Auto”.

6.17.1.3.4 Verify PEEP valve is at minimum (counter-clockwise).

6.17.1.3.5 Set O_2 Flow to 8 l/min.

6.17.1.3.6 Occlude the bottom 19 mm connector (EXHAUST).

6.17.1.3.7 After the bellows inflates, the flow of oxygen will exit the system through the positive pressure safety relief valve.

6.17.1.3.8 Is the pressure displayed on absorber cm H_2O gauge is less than or equal to 5 cm H_2O?___(Y)

(✓) 6.17.2 Scavenger - Suction Mode

6.17.2.1 Remove the scavenger hoses and drain all accumulated moisture. Inspect all scavenger hoses and scavenger bag for deterioration and replace as necessary. Reinstall hoses and bag.

6.17.2.2 Remove the filter from the negative pressure relief valve. Clean and reinstall the filter.

6.17.2.3 Negative Pressure Test:

6.17.2.3.1 Interconnect the inspiratory valve and expiratory valve or expiratory port on the ultrasonic flow sensor, if applicable with a 22 mm hose (P/N 9995132).

6.17.2.3.2 Set Man/Auto valve to “BAG” position

6.17.2.3.3 Fully open APL valve.

6.17.2.3.4 Attach a Breathing System Leak Test Device (P/N S010159) to the bag mount (occlude bag mount).

6.17.2.3.5 Verify Suction system is active. Adjust needle valve to allow typical suction through scavenger.

6.17.2.3.6 Verify all flow control valves are closed.

6.17.2.3.7 Install scavenger adapter (P/N 4108114) between either of the 19 mm scavenger connectors and scavenger hose. Connect a manometer to the hose barb on the scavenger adapter and observe reading on manometer. The manometer shall indicate a pressure less than or equal to 0.5 cm H_2O.

6.17.2.4 Positive Pressure Test:

6.17.2.4.1 Fully close scavenger needle valve.

6.17.2.4.2 Push the O_2 flush to inflate scavenger bag. Open oxygen flow control valve to 8 l/min.

6.17.2.4.3 Verify reading on manometer is less than or equal to 5 cm H_2O.

6.17.2.4.4 Remove all test equipment. Adjust scavenger needle valve to allow typical suction through scavenger.

6.18 FINAL TESTS

(✓) 6.18.1 Is the machine's Operator's Instruction manual in close proximity of the machine? ___ (Y)

6.18.2 Verify all cylinder pressure gauges indicate zero.

6.18.3 Verify the pipeline hoses are connected to the hospital pipeline.

6.18.4 Verify the APL valve knob is turned completely counterclockwise (fully open).

6.18.5 Place the AUTO/BAG selector in the BAG position.

6.18.6 Verify the ventilator hose is connected between the AUTO/BAG valve and bellows ventilator hose terminal.

6.18.7 Verify the Breathing Pressure Sensor line is connected to the Breathing Pressure interface on the machine.

6.18.8 Verify the Oxygen sensor is removed from the inspiratory valve dome.

6.18.9 Verify that the Inspiratory valve dome is plugged.

6.18.10 Verify that the machine is plugged into a live A/C receptacle.

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